Exploring the Gap Between a Morally Valid and a Legally Adequate Consent: Investigating Latino Understanding of an Informed Consent Conference

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Dedication

I dedicate this dissertation to my husband, mi amor, mi cielo, gracias por tu apoyo, las cenas deliciosas, tu oído atento, y más de todo, tu amor.

Abstract

Enrollment of members of minority communities in clinical trials is an important step towards the elimination of health disparities and increases the generalizability of research results. Latinos are disproportionally affected by a number of health issues such as diabetes. Having Latinos participate in research is essential since limited participation leads to limited data specific for this population. Furthermore, for some patients, inclusion in clinical trials represents an opportunity to receive new therapies not otherwise available.

This project explores Latinos' understanding of the informed consent conference considered on a broad level, including oral, textual, and visual components. Grounded theory is used as the analytic methodology. This bioethics question is explored by situating the theory within relevant literature in bioethics, rhetoric, scientific and technical communication, and intercultural communication.

Data was gathered in three studies using the methodology of analogue participants. A simulation of a healthy patient consent conference was used in Study 1 and Study 2, while a simulation of a multi-arm diabetes trial was used in Study 3. The analogue participants were recruited from urban Catholic parishes that serve a large immigrant Latino population.

In order to secure a moral consent and honor the autonomy of members of this community during trial enrollment, the researcher must thoroughly understand the social context that forms the identity of the Latino community member. Although the level of autonomy varies with each individual, the social context shaped by this data suggests a compromised autonomy.

The social context of this community is complex and dynamic. Latino immigrants in this study live in a closely-knit community, sharing a culture, language, faith, for the most part their country of origin, and the immigrant experience. These community members demonstrate care and concern for one another in their shared

struggles to acculturate while living with a steady sense of disquietude surrounding the immigration status of themselves, family members, or friends. An undocumented status affects all areas of an immigrant's life, limiting many potential opportunities.

The grounded theory resulting from the data gathered in Study 1, Study 2, and Study 3 suggests a culturally specific way to present trial information to members of this community, describes how that information might be understood, and illustrates the community's social context. Understanding the social context is necessary to understand how to present trial information and to understand the autonomy of community members.

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Chapter 1: Introduction

Donde hay gana, hay maña[1]

Where there is the desire, there is the ability.

While there has been much research on informed consent generally, little has been done to explore the process with Latino immigrants with limited or no English language skills. This project explores Latinos' understanding of the informed consent conference considered on a broad level, including oral, textual, and visual components. Grounded theory will be used as the analytic methodology. This bioethics question is explored by situating the theory within relevant literature in bioethics, rhetoric, scientific and technical communication, and intercultural communication. The roles played by each discipline are the following:

- Ethical principles ground the question
- Rhetorical analysis helps understand the community
- Technical communication creates the consent process
- Intercultural communication refines the process

The overarching question I am looking to answer is this: How do Latino immigrants with little to no English language proficiency negotiate a clinical trial informed consent process? Specifically, the research questions that will inform this inquiry are:

R1: What do Latino immigrants understand from the informed consent process?

R2: Is there information important to the participants that is not being communicated?

R3: How adequate is the structure of the consent conference?

[1] Each section of each Chapter begins with a *dicho* (saying, proverb). A *dicho* is a popular adage that serves to pass on important Mexican cultural values. A *dicho* is a form of epideictic rhetoric.

Terminology

Gómez-Peña (1993), a Chicano activist, writer, and performance artist, feels strongly about the terms we use to describe people: "Terms like Hispanic, Latino, ethnic, minority, marginal, alternative, and Third World, among others, are inaccurate and loaded with ideological implications. They create false categories and neo-colonial hierarchies. In the absence of a more enlightened terminology, we have no choice but to utilize them with extreme care" (p. 46).

I have chosen to use the term *Latino* when referring to individuals with origin or ancestry from a Spanish-speaking country including Mexico, Central America, South America and parts of the Caribbean. As explained by Albert (1996), among others, the label *Hispanic* is a term created by the government of the United States (U.S.) and to some incorrectly emphasizes Spanish origins. *Latino* is a more inclusive term that attempts to acknowledge the roles of indigenous peoples and African cultures in the histories of these Spanish-speaking countries (Albert, 1996; Flores, 2000).

Note, however, that a 2013 Pew Research report (Lopez, 2013) shows that 54% of Hispanics report a preference for using the name of their or their ancestor's country of origin, while 23% describe themselves as American. Only 20% use the term *Hispanic* or *Latino* to describe themselves. According to a 2013 survey, 50% of Hispanics report no preference between the terms *Hispanic* or *Latino*. Of those who do have a preference, 33% prefer *Hispanic* and 15% prefer *Latino* (Lopez, 2013).

An article in *Language and Intercultural Communication* (Valdeón, 2013), explores the distinction between the two terms both in government use and in the mass media. The term *Hispanic* was first used by the American Census Bureau in the 1970s while the term *Latino* "was probably an act of defiance and only by part of the minority" (p. 439). While the term *Latino* was a response to bureaucratic labeling, "the term, even today, is not widely accepted and used by the Hispanics at large" (p. 439).

Significance of the Topic

Enrollment of members of minority communities in clinical trials is important for a number of reasons. Research that includes minorities works towards the elimination of health disparities and increases the generalizability of research results. This study looks specifically at Latinos, who, as reported by the Pew Hispanic Center, represent the largest, fastest growing ethnic group in the U.S., numbering 50.5 million, or 16.3% of the total population in the United States (Cohn, Passel,& Lopez, 2011). Latinos, it has been reported, have a high prevalence of diabetes and obesity (Cohn, Livingston & Minushin, 2008; Vivo, Krim, Cevik, & Witteles, 2009), dyslipidemia (having too high or too low lipid levels in the bloodstream), metabolic syndrome, and hypertension (Vivo, et al. 2009). Another consideration is the fact that drug pharmacokinetics (the interactions of a drug and the body in terms of its absorption, distribution, metabolism, and excretion) and pharmacodynamics (the effects of drugs on the body and the mechanism of their action) vary among racial and ethnic populations.

Therefore, having Latinos participate in research involving these and other health issues is essential since limited participation leads to limited data specific for this population. Furthermore, for some patients, inclusion in clinical trials represents an opportunity to receive new therapies not otherwise available.

A researcher has a legal and moral obligation to obtain informed consent from the research participants. The concept of informed consent is detailed in the *Belmont Report*. Introduced in 1979, the *Belmont Report* is a result of hearings of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[2]. The report outlines three basic principles that direct the conduct of biomedical and behavioral research that utilize human subjects: respect for persons, beneficence, and justice. It also provides concepts that serve to guide researchers adhering to these principles. The *Belmont Report* lays out specific applications of the

[2] A brief overview of the history of the field of bioethics, including a history of informed consent is provided in Chapter 2: Interdisciplinary Literature.

three general principles. The process of informed consent operationalizes the principle of respect for persons and contains three elements:

1. Information: describes what sort of information should be provided. The items generally included are descriptions of the procedure, purposes, risks and benefits, and alternative procedures. Additionally, subjects are given the opportunity to ask questions and the opportunity to withdraw from the research.
2. Comprehension: includes issues of the adaptation of the information and allows special provisions for those who may have limited comprehension.
3. Voluntariness: includes issues of coercion.

This project will be limited to persons assumed to be capable of self-determination. However, as Wendler (2004) reports, "data that show that research subjects with no known cognitive impairments, the majority of whom presumably have the capacity to give valid informed consent, often fail to do so in practice" (p. 2202). Being capable of self-determination does not necessarily negate the need for some degree of protection, or at minimum, extended considerations. Recruiting members of immigrant communities may be considered in the category of, what the *Belmont Report* names, "hard cases" (Belmont Report, 1979, Part B. 1., para. 6).

With the disclosure of the required information the patient or trial participant is considered informed and may now make an informed choice as to whether or not they will participate in the medical procedure or clinical trial. The *Belmont Report* states that the "Investigators are responsible for ascertaining that the subject has comprehended the information" (Belmont Report, 1979, Part C. 1., para. 6).

A Morally Valid Consent

The title of this project makes a distinction between legal consent and moral consent. Legal consent means the researcher has followed their Institutional Review Board (IRB) requirements regarding the consent conference, that the potential participant has agreed to take part, and that a signature was obtained. Moral consent, as I am using the term in this project, means that the researcher has disclosed necessary information, has ensured that the participant fully comprehends the information, has had the opportunity to ask for additional information or clarification they may need, and is freely agreeing to participate. The difference is that great care is taken to understand the potential participants and what they may need to truly understand the information disclosed. In the case of immigrant Latinos, there are many barriers to achieving a moral consent.

Overall, there are several challenges immigrant populations may face that could affect the process of fully grasping disclosed information.

Comprehension can be difficult for recently immigrated persons who have limited English language skills and may have limited formal education. They may be unfamiliar with the medical system in the U.S., may be unfamiliar with Western medicine, and may be unfamiliar with the concept of research. Additionally, they may have limited knowledge of the etiology and the nature of their disease and be unfamiliar with medical and physiological vocabulary.

Cultural factors may interfere with understanding the informed consent information. For example, the notion of autonomy may pose difficulty for a variety of reasons. Mexico and Latin America rank high in power distance, meaning that there exists a clear social hierarchy (Hofstede, 1994). Implications of this power distance dimension may be that information presented by a person of respected status, such as a health care provider, be accepted without question. Simon et al. (2003) have noted that in their study parents in the non-English speaking group asked fewer questions than

members of the other two groups that were studied. "Prevailing Latino cultural norms that encourage passivity, such as *respeto* (respect) and *fatalismo* (fatalism), may contribute to this disparity. In addition, lower social and economic status in immigrant populations frequently correlates with high adherence to traditional values" (p. 2177).

All of these factors add complications to the execution of the elements of informed consent. The conventional topics presented in a conventional manner may be incomprehensible to members of the immigrant community. What may be needed is background information, explanations, definitions, and, significantly, time. Katz (1993), while discussing potential problems experienced by a physician investigator makes points valid to this discussion. He observes that "current informed consent forms often provide IRB's rather than the subjects with a better understanding of investigators' intentions" (p. 36). In other words, the forms are overly technical and written at higher reading level than is appropriate. Additionally, from the standpoint of the immigrant population, these forms may not contain all of the information that may be needed. Katz (1993) notes that to follow his recommendations on how best to secure a morally valid consent (as compared to a legally adequate consent), takes time and "may have to extend over hours, perhaps even days, and must be continued until one is reasonably certain that the patient-subjects understand" (p. 36). This investment in time would certainly improve the consent process of immigrant populations by demonstrating a concern for the individual and a willingness to have a conversation, a more equal sharing in power. This would provide an environment where questions could be asked and concerns aired. Simply translating the information into the native language does not necessarily make the information more understandable. *The Belmont Report* recognizes that "[t]he manner and context in which information is conveyed is as important as the information itself" (Belmont Report, 1979, Part C. 1., para. 6). How best to adapt the information for an immigrant audience is a complex question.

Another difficult and complicated task is determining comprehension. The *Belmont Report* stipulates that "Investigators are responsible for ascertaining that the

subject has comprehended the information" (Belmont Report, 1979, Part C. 1., para. 7). However, the *Belmont Report* does not give much guidance on how to do this. The report does mention cases where the presentation of the information should be adapted. Such cases include "conditions of immaturity or mental disability." There is no mention, however, of any instance resembling that of enrolling members of immigrant populations. Situations involving individuals who are non-native speakers and are from a different culture are not addressed most likely because it was not a consideration at the time the *Belmont Report* was authored. While there has been much research done on this question of comprehension (e.g. Jefford & Moore, 2008; Stunke et al., 2010; Sudore et al. 2006), very little has been done that focuses on members of immigrant communities. Though the clinical trial researcher is charged with ensuring the trial participant understands the information presented, the extent of understanding is poorly understood, especially in the immigrant population who are non-native speakers.

It is important to recognize that the status of the researcher and the status of a potential research subject from the immigrant community is often unequal. Members of the immigrant communities are often poor, with little education. Sherwin (1998) points to the strength of the principle of autonomy, "A principle insisting on protection of patient autonomy can be an important corrective to such overwhelming power imbalances" (p. 22). However, she also acknowledges that determining how a power imbalance interferes with autonomy is not well understood.

The case study described by Martin and Lantos (2005) illustrates the result of inadequate communication. Martin and Lantos conducted community based research[3] in a Latino community in Chicago where they were attempting to evaluate a community health worker asthma intervention program. This critical methodology can be effective in eliminating power issues. In this case study, the researchers created a consent form using plain language translated into Spanish, to be administered orally to account for low

[3] Community based research is discussed in Chapter 2, "Scientific and Technical Communication."

literacy. However, their IRB insisted that they directly translate the four-page consent form containing complex legal terminology and complex English. The two Latino agencies that were working with the researchers assured the researchers that most potential subjects would not be able to understand the form, but they would sign it anyway. This illustrates the ethical dilemma of melding a morally valid with a legally adequate consent.

The project described in this document explores this dilemma beginning with Chapter 2: Interdisciplinary Literature, which provides an overview of the literature that informs this topic and this research project. The fields represented in this review include bioethics, rhetoric, scientific and technical communication, and intercultural communication. In Chapter 3: Study 1, the first study in this project is described including the methods, results, and discussion. Two methodologies are introduced that will be used in this and the subsequent studies in this project: grounded theory and analogue participants. This study uses the materials from a healthy patient trial for the simulation. Chapter 4: Study 2 continues data gathering at a second location using the same methodologies and trial materials. Chapter 5: Study 3 describes the final study in this project. This study continues to utilize the methodologies of grounded theory and analogue participants. However, instead of using the materials from the healthy patient trial for the simulation, the materials from a multi-arm, multi-site diabetes trial were used for the simulation. In Chapter 6: The Grounded Theory: Informed Consent as a Form of Technical Communication, the grounded theory resulting from the data from all three studies is explained in full including a final version of a conceptual framework. Finally, Chapter 7: Implications, Research Quality, Limitations, Future Research discusses the implications of this research, the quality and the limitations of the research, and future research directions.

Chapter 2: Interdisciplinary Literature

El que por su gusto corre, nunca se cansa

Who for his pleasure runs, never tires

This research project examines the adequacy of the informed consent process when members of the immigrant Latino community are recruited into clinical trials. This bioethics question is being explored using a multidisciplinary lens, situating it at the intersection of bioethics, rhetoric, scientific and technical communication, and intercultural communication. This project is complex and interdisciplinary and as such the possibilities of available literature are imposing. I have attempted to set forth specific histories, notions, and theories within each discipline that are relevant, necessary, and useful to analyze or describe the emergent theory.[4] The first section in this chapter, Bioethics, will describe the origins of informed consent. The following sections, Rhetoric, Scientific and Technical Communication, and Intercultural Communication—Latino Culture, describe aspects of those disciplines that are necessary to fully understand and analyze how informed consent is functioning with immigrant Latinos with little to no English language skills.

Bioethics

In this section, I provide a brief overview of the field of Bioethics, including the involvement and contributions various disciplines have made in the development of the discipline called bioethics. The research questions are bioethical questions, being examined using bioethical theories and other disciplines. To understand the importance of an ethical informed consent, a moral informed consent, it is important to understand how it functions within the field. The following history of bioethics locates informed consent and describes its function as it was originally conceived.

[4] Literature on the use of interpreters, translation, recruiting and retaining minorities in clinical research and international clinical trial research are not included in this literature review.

Callahan defines bioethics as "the application of ethical theory to the dilemmas raised by the practice of modern medicine, especially those problems raised by the applications of new technologies" (as cited in Hedgecoe, 2004, p. 122). Hedgecoe intends this definition to include medical ethics, clinical ethics, research ethics, and biomedical ethics. The evolution of this field has involved influences from many disciplines beginning with philosophy and theology. Jonsen explains that "theology and philosophy presided over the birth of bioethics and shaped the bioethical movement. Each brought a distinct tradition and perspective together with analytic skills sharpened by their disciplines. Together they produced an amalgam of ideas, methods, and educational structures that became bioethics" (as cited in Borry, Schosmans, & Dierckx, 2005, p. 50). Physicians, nurses, lawyers, and more recently, social scientists, have also played consequential roles in shaping the discipline.

Prior to the awareness of human subject research abuses (described more fully in the subsection, "The regulatory history of informed consent") and prior to the advent of modern medical procedures and technologies, an ethic within medicine served to inform the conduct of physicians. However, as medicine evolved a new ethic was needed to reflect the new possibilities. Additionally, the public and political climate of the time was influential. Belkin and Brandt (2001) explain this influence, "The reaction to abuses, the new expectations of clinical practice, and the rise of bioethics can…be fully understood only in the broader context of the rights-based movements for self-determination in the 1950's and 1960's" (p. 3). Alongside the awareness of past human subject abuses, current events such as the Karen Ann Quinlan case and the evolving definition of death as proposed by a group at Harvard Medical School were publicized. This new definition was of death was "brain death" as opposed to death being the cessation of cardiopulmonary function, and was created as a direct response to the first organ transplant (heart) in 1967. Will (2011) points out that "definitions of death are not solely the province of medicine; they also include questions of social, theologic, and philosophical significance" (p. 1495).

Though theologians played central roles in the development of the discipline of bioethics, as the discipline progressed a more secular framework was sought. It is logical, in light of the rights-based focus of the time, that autonomy became a central principle, along with the principles of beneficence, nonmaleficence, and justice (Belkin & Brandt, 2001; Beauchamp & Childress, 1979). These principles comprise a normative ethic, termed principlism, which still retains its place as a central moral theory in the field. However, this approach is not without criticism. Charges levied include the absence of a larger moral theory (Belkin & Brant, 2001), the lack of attention to narratives of illness (Brody, 1987; Nelson, 2004), the lack of attention to relationships, power distribution, and gender roles (Lindemann, 2006; Sherwin, 1998; Walker, 1998; Warren, 1989), and the lack of incorporation of social and cultural scholarship (Fox & Swazey, 2008). The focus on individualism and traditional autonomy theory can be placed in opposition to a more contextualized view of autonomy, creating a tension that interferes with the integration of the social and cultural perspective into bioethics. Moreover, there are issues with the concepts of universalism and particularism, with an "intellectual and moral preference for universalism, in the form of transcendent principles that 'rise above' the particularities of historical circumstance and traditions, and of social and cultural context and locale" (Fox & Swazey, 2008, p. 158).

In an attempt to address these criticisms and place moral issues in a social, cultural, and historical context, alternative moral theories have come into use. Among these approaches are feminist ethics, communitarianism, narrative ethics, virtue ethics, casuistry, and urban bioethics. These approaches bring with them a variety of social science disciplines that are being incorporated into bioethical research. Borry, Schosmans, and Dierckx (2005) hypothesize that this is due to three factors: critiques to the foundationalism approach in applied ethics, an interest in empirical research by clinical ethicists, and the emergence of evidence-based approaches in healthcare.

Empirical research done by social scientists has aided in the acceptance of sociology and anthropology within the discipline of bioethics. DeVries (2003) considers

the relationship of sociology and bioethics as a continuum moving from descriptive ethics (sociology in bioethics) to studies that explore the context of bioethics (sociology of bioethics). The focus of sociology's work is not on the principles of bioethics, but rather on the socially constructed meanings. "Seen from the point of view of sociology, the [bioethical] principles are empty vessels into which cultural meanings are poured. Sociologists are more interested in how the vessel was created and what is put into it then they are in the vessel itself" (DeVries, 2003, p. 186). Turner (2003) notes that by the mid-1990s, cultural norms and ethnic differences became legitimate sites of enquiry, creating a richer context for research.

The history of informed consent includes contributions from law and moral philosophy (among others as described in the preceding paragraphs). The law's initial involvement was concerned with the clinical use of informed consent (as opposed to consent used for research), focusing on monetary compensation for patients harmed by a physician's failure to disclose pertinent information or a disregard of patient's wishes. In moral philosophy, informed consent is concerned with respect for the autonomy of the patient or research participant (Faden & Beauchamp, 1986).

The next subsection, "Evolution of the legal doctrine of informed consent—landmark cases," is by no means exhaustive as much is not discussed with respect to legal complexities. The intent is to provide an abbreviated overview of the path that has led to modern informed consent in clinical medicine. An understanding of the historical roots is an essential foundation for thinking about a theory of informed consent. Faden and Beauchamp (1986) point to the function of the courts saying, "Their [courts] primary goal is the secure, after-the-fact resolution of narrow and concrete questions of duty, responsibility, blame, injury…in specific cases" (p. 115). As a result, they conclude, the body of decisional law that has amassed "tends to be both repetitive and incomplete, with its theory [of informed consent] strikingly unsettled" (Faden & Beauchamp, 1986, p. 115).

Evolution of the legal doctrine of informed consent—landmark cases. This section provides a brief summary of the landmark cases that comprise the legal doctrine of informed consent in the United States.[5] Pernick, a medical historian, found no battery cases prior to 1889, causing him to conclude that the nineteenth-century legal system saw the court's enforcement of informed consent as representing the moral principle of beneficence, not the principle of autonomy. Consent at that time was considered a part of the therapeutic process; therefore, unless a medical expert stated that consent was a beneficial part of therapy, it was not enforced, nor even considered (as cited in Faden & Beauchamp, 1986). Will (2010) agrees, observing that prior to the turn of the twentieth century "the beneficence model, a paternalistic approach to the practice of medicine whereby physicians exercise decision-making authority within the relationship at the expense of patient self-determination" (p. 1491) was the dominant model. Therefore, the history related here begins in the twentieth century.

Four battery cases heard between 1905 and 1914 are credited for detailing the basic features of informed consent. The first case, *Mohr v. Williams* (1905), involves an incident where Anna Mohr gave consent for her physician to operate on her right ear. During the surgery, he decided her left ear was in need of surgery and operated on her left ear, causing damage. The court ruled that a physician must have explicit consent for the specific procedure, and with that consent the physician "enters into a contract" authorizing him "to operate to the extent of the consent given, but *no further* [emphasis added]" (as cited in Faden & Beauchamp, 1986, p. 121). This ruling also, importantly, assumed that consent includes disclosure of applicable dangers and risks.

In the second case, *Pratt v. Davis* (1906), the physician performed a hysterectomy without the patient's consent. A lower court rejected the defense's argument that simply employing a physician implies consent to whatever treatment the physician determines is needed. The higher court upheld the decision, which among other specifics, forbade

[5] For a complete listing of relevant cases along with case summaries see http://www.lawandbioethics.com/demo/Main/LegalResources/C5/background01.htm.

implied consent except in emergencies. Note that the lower court's final opinion in the *Mohr* case came after the lower court ruling in the *Pratt* case. The *Pratt* case was cited during the *Mohr* case.

Rolater v. Strain (1913), the third case, involved the physician removing a bone from a patient who had consented to surgery to drain an infection of the foot, but specified that no bone was to be removed. Here the court's reasoning from *Mohr* and *Pratt* was extended to the facts of this case. Now, even though the physician had consent for that particular body part, there was no specific consent for the procedure to remove the bone.

In perhaps the most well-known clinical consent case, *Schloendorff v. Society of New York Hospitals* (1914), concerns Mrs. Schloendorff who had gone to the New York Hospital complaining of a stomach disorder. Her doctor believed she was suffering from a nervous disorder and gynecological problems so he suggested an 'ether exam' reasoning she was too nervous to undergo an exam while awake. During the exam the doctor performed a hysterectomy without Mrs. Schloendorff's prior knowledge or consent (Dolgin, 2010).

Though the judge presiding over the *Schloendorff v. Society of New York Hospitals* case, Justice Cardozo, said nothing specifically about consent, his opinion is often quoted in the consent literature:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages" (as cited in Faden & Beauchamp, 1986, p. 123).

This important statement declares that patients have the right to protect their bodies and deny consent, even if the rejected procedure would have proved to be beneficial. Faden and Beauchamp (1986) note that the legal precedents resulting from

the decisions of each of these four cases created "the battery theory of liability as grounded in a right of *self-determination* [emphasis added]" (p. 123). This decision was presented using the language of assault and battery, describing the violation as intentional, offensive touching.

The next defining case was *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957) involving Marin Salgo, who had suffered permanent paralysis as a consequence of a lumbar aortography. Salgo had not been told that paralysis was a possible risk of this procedure. He sued for both negligence and the failure to disclose the risks of the procedure. The court concluded "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts…necessary to form the basis of an intelligent consent by the patient to the proposed treatment." The court then added that physicians could withhold facts depending on the patient's "mental and emotional condition" (as cited in Dolgin, 2010, p. 98).

What is significant in this case is that the court's focus was not just proving that consent had been given, but that all pertinent information had been disclosed. This case was the first time the term "informed consent" was used. This reasoning resulted in a ruling of malpractice (negligence) rather than battery, though the precedents cited, including *Schloendorff v. Society of New York Hospitals*, were battery cases. It also, significantly, attempted to balance patient autonomy with physician interests by introducing physician discretion.

Though the *Salgo* case was defining in moving the battery theory to liability based on negligence, cases continued to be decided as battery. In *Gray v. Grunnagle* (1996), the plaintiff had been paralyzed after an exploratory laminectomy. He claimed he had not been told about the risk of paralysis. The court, similar to the *Mohr* case, referred to the "quasi-contractual physician-patient relationship" (as cited in Faden & Beauchamp, 1986, p. 128). Following this ruling was a second case resulting in a battery ruling, *Berkey v. Anderson* (1969). Here the patient was not told of the risks involved in a

myelogramn or and that a spinal puncture would be employed, but rather, was told myelograms were merely diagnostic. The court's decision in this matter "linked the duty of disclosure to the law of fraud and deceit, as *Pratt* had done" (Faden & Beauchamp, 1986, p. 128).

Lastly, was the case of *Cooper v. Roberts* (1971). In this case, the patient was not informed of the possibility of a stomach puncture by the instrument used in a diagnostic examination. The court, in its ruling used a "reasonable person standard." This standard looks at what "information the 'reasonable person' needs to know about risks, alternatives, and consequences" (Faden & Beauchamp, 1986, p. 132).

Three court decisions in 1972 solidified the legal concept of informed consent: *Canterbury v. Spence* (1972), *Cobbs v. Grant* (1972), and *Wilkinson v. Vesey* (1972). *Canterbury v. Spence* (1972) involved a patient who had undergone a laminectomy procedure for severe back pain. He was left with lasting negative health effects, though "Canterbury's postoperative story as told to the court was rather confused" (Dolgin, 2010, p. 100). The trial court did not find Spence negligent; however the appellate court did, finding Spence negligent of disclosing the possible risk of serious disability (Dolgin, 2010). The judge quoted *Schloendorff v. Society of New York Hospitals* and concluded that a physician has the duty to both disclose information such as viable options and risks as well as the duty of due care. (Faden & Beauchamp, 1986). *Canterbury v. Spence* (1972) was noteworthy in its demand for a patient-oriented standard of disclosure, the 'reasonable person' standard. "The court required a physician to disclose information that a reasonably prudent person would find 'material' in deciding whether to consent to a proposed form of care" (as cited in Dolgin, 2010, p. 101). What was important was that the court stipulated the information be put forward to meet the needs of a reasonable person, rather than the needs of a particular patient. The other two cases heard that year, *Cobbs v. Grant* (1972) and *Wilkinson v. Vesy* (1972) relied heavily on language used in *Canterbury*.

Beauchamp (2011) observes that a precise description of informed consent is complicated because two different meanings have been at work throughout its history. The first,

> "is an autonomous authorization by individual patients or subjects. A person gives an informed consent in this first sense if and only if the person, with substantial understanding and in substantial absence of control by others, intentionally authorizes a health professional to do something…in the second sense, informed consent is analyzable in terms of *institutional and policy rules of consent* that collectively form the social practice of informed consent in institutional context. Here 'informed consent' refers only to a legally or institutionally effective approval given by a patient or subject" (p. 518).

Within the legal context informed consent is concerned with the second sense, but does little to move the concept toward the first sense. Bioethics literature maintains that it is this first sense, autonomous choice by medical patients or research participants that must be maintained. This is the "morally best standard" (Beauchamp, 2011, p. 518) and provides a model for institutional and policy requirements of informed consent.

The next subsection, "The regulation history of informed consent," follows a path that began with the Hippocratic Oath, was shaped by the Nuremberg Code, and was followed by the Declaration of Helsinki resulting in modern informed consent as it applies to research with human participants. As with the subsection that traces the legal doctrine, the subsection on the regulation history is not exhaustive. The intent is to provide an abbreviated overview to better understand how informed consent in research settings came about. It is written in a linear fashion for ease of presentation, though it should be recognized that the detailed history is much more complex.

The regulatory history of informed consent. The earliest writings in Western medicine are thought to be the *Corpus Hippocraticum*, written in ancient Greece and

providing instruction on medical professional conduct. There is no mention in these texts of obtaining consent. These writings follow the beneficence model, or more precisely, the nonmalificence model, urging physicians to *primum non nocere*—first do no harm (Faden & Beauchamp, 1986). The history described in this subsection will not be exploring these ancient roots, nor looking at the history of medieval or enlightenment medicine. The history will begin with *The Nuremberg Code*.

The Nuremberg medical trial, *U.S.A. v. Karl Brandt et al.*, began on December 9, 1946. The trial focused on both the human subject experimentation performed under the Nazi regime and an active euthanasia program for those with physical and mental disabilities. On trial were some of Germany's most eminent medical scientists. In total, 23 defendants stood trial—20 physicians and three key administrators who held positions in the Fürher's chancellery, Reich Ministry of the Interior, and the Institute for Military Scientific Research ("Part II" Shevell, 1998). The trial, which lasted until August 1947, brought to light the chilling details of the atrocities inflicted on imprisoned human subjects.

In the opening statement for the prosecution, U.S. Chief of Counsel for War Crimes Telford Taylor began with the following declaration,

> The defendants in this case are charged with murders, tortures, and other atrocities committed in the name of medical science. The victims of these crimes are numbered in the hundreds of thousands. …most of these miserable victims were slaughtered outright or died in the course of the tortures to which they were subjected (Taylor, 1992, p. 67).

On August 19, 1947, the presiding judge, Judge Walter Beals, handed down rulings against 16 of the defendants, which included seven death sentences ("Part II" Shevell, 1998). As part of the judgment, a code was introduced that listed 10 basic principles intended to govern the use of human subjects in medical research and

experimentation. (Temme, 2003, p. 1297). This code is now commonly referred to as the *Nuremberg Code* (see Appendix A).

Judge Beals introduced the code with the following statement,

> The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that *certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts* [emphasis added] ("Judgment and Aftermath," 1992, p. 102).

While the *Nuremberg Code* was applauded by United States (U.S.) researchers, they considered it inapplicable to them. Researchers were slow to recognize the need for such regulations to be applied in the U.S. In fact, Andrew Ivy, credited to have authored the code along with Leo Alexander, was sent to the Nuremberg trials by the American Medical Association (AMA) in part to make sure that human experimentation in the U.S. could continue. In a telling statement made in 1964, Ivy states,

> I accepted the invitation to serve at the Nuremberg trials only because I had in mind the objective of placing human beings may serve as subjects in a medical experiment (sic), so that these conditions would become the international common law on the subjects. Otherwise I would have nothing to do with the nasty and obnoxious business. I believe in prevention, not a 'punitive cure' (as cited in Temme, 2003, p. 1298).

Also condemning the atrocities performed by the Nazi doctors, physicians from the World Medical Association (WMA) issued a code of ethics in 1949 called the

Declaration of Geneva. This work was subsequently clarified and revised in 1964, becoming what is known as the *Declaration of Helsinki*. This declaration defines human research and its necessity while stressing the obligation of the physician to set the health of the participant as the priority; it puts forth basic principles for medical research and discusses research combined with medical care (Fischer, 2006). Since its inception the *Declaration of Helsinski* has been revised several times, most recently in 2013 (”WMA Declaration of Helsinki”, n.d.)

Neither the *Nuremberg Code* nor the *Declaration of Helsinki* were adopted into U.S. law. Medicine at the time was essentially a paternalistic field, with no disclosure requirements mandated for physicians. Modern informed consent was essentially imposed on the medical field through law courts (as shown in the previous subsection, “Evolution of the legal doctrine of informed consent—landmark cases).” The National Institutes of Health (NIH) issued its first consent policy in 1953 when it opened the NIH Clinical Center to conduct biomedical research under the sponsorship of the federal government (McCarthy, 1998; Williams, 2005). Though the center required informed consent and project peer review for healthy volunteers, patient participants were not afforded these considerations (McCarthy, 1998). This first example of protections for research participants was not, unfortunately, adopted by “other federal or private institutions” (Faden & Beauchamp, 1986, p. 202).

Faden and Beauchamp (1986) describe early federal initiatives in research that involved human participants. In 1962, the U.S. Congress passed the Drug Efficacy Amendment motivated in part by the effects of the sedative Thalidomide,[6] used in Europe, though not approved in the U.S. This drug caused children born to women who took this drug while pregnant to have malformed limbs. The amendment called for new

[6] Thalidomide was originally introduced in Germany and prescribed for its sedative effects. At the time it was thought to be non-toxic. However, no testing had been done on pregnant lab animals prior to its release. An examination of the testing confirmed “that the preclinical tests on thalidomide were superficial, and there is no doubt that it was never administered to pregnant animals prior to its use in patients” (Botting, 2002, p. 604).

federal regulations, among them the requirement that researchers and physicians inform research participants or patients of a drug's experimental status and obtain their consent for its use; albeit with a provision that consent was not necessary in the case where researchers, in their best judgment, thought it not feasible or not in the best interests of the participant (Faden & Beauchamp, 1986, p. 203). At this point the U.S. Food and Drug Administration (FDA) authored new regulations, of which "[a] substantial portion of the regulations was directed exclusively at research design and procedures" (Faden & Beauchamp, 1986, p. 204). However, the consent requirement mirrored the new law and included the physician's discretion provision. Also, these FDA regulations did not apply to all research, only to research with "experimental drugs, devices, and biologics" (Faden & Beauchamp, 1986, p. 205).

In 1960, the NIH awarded the Law-Medicine Research Institute at Boston University a grant to conduct a three-year study "to examine the ethical, legal, and moral issues of research practice in the United States" (McCarthy, 1998, p. 18). The result of the study found that only 16 of 86 departments of medicine in U.S. medical schools used forms to document informed consent (McCarthy, 1998). While the NIH was considering how best to proceed, the *Declaration of Helsinki* was adopted by the WMA in 1964. Another defining event in this history was a publication written by Henry Beecher, a professor of anesthesiology at Harvard's Massachusetts General Hospital, who was himself engaged in human research. He reportedly had followed the Nuremberg medical case closely and recognized that research currently ongoing in the United States might also be exploiting participants. He wrote several articles on the subject. Considered a landmark in the history of informed consent, his article "Ethics and Clinical Research," was published in 1966 in *The New England Journal of Medicine*. In this article he names 22 postwar research studies of "unethical or questionable ethical studies" (Beecher, 1966, p. 1355), with only two utilizing informed consent.

Unethical studies had indeed taken place during the 1930s–1950s in the U.S., though most did not come to light until much later. Will (2010) notes "most wartime

research was performed in the United States on the institutionalized poor, orphans, prisoners, the mentally disabled, minorities, and the like, without consent" (p. 1494). Some of these studies are known by the institutions where they took place such as Willowbrook and the Jewish Chronic Disease Hospital. The most well-known of these grossly unethical research studies began in 1932 in the town of Tuskegee in Macon County, Alabama. This study was led by the U.S. Public Health Service for the purpose of observing the natural progression of syphilis in African American men. The study enrolled 399 men with syphilis and 201 uninfected men who were to serve as controls. The infected men were never told they had syphilis. They believed they were receiving free medical care for a condition colloquially known as 'bad blood'. Even when penicillin became available as a known treatment for syphilis in the early 1950s, the participants in this study were not offered treatment (Brandt, 1978). Astonishingly, this study continued despite being regularly and widely published in the medical press. Jean Heller, a reporter with the Associated Press broke the story about this study in 1972, 40 years after its inception and 19 years after the discovery of penicillin as a treatment. The study was ended in November 1972 by the Assistant Secretary of Health and Scientific Affairs (Williams, 2005). On May 26, 1997, President Clinton publically apologized to the few survivors and provided monetary compensation to them and the heirs of the deceased (McCarthy, 1998).

The Senate Health Subcommittee held many hearings concerning not only the Tuskegee Syphilis Study, but also fetal research, psychosurgery and other health topics. Although it was in large part in response to the Tuskegee Syphilis Study that Congress passed the National Research Act (P.L. 93-348) on July 12, 1974, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (McCarthy, 1998). This commission issued a report in 1979, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, more commonly known as the *Belmont Report*. I will examine this report further in the next subsection, but briefly it named three principles that should underlie ethical research with human subjects: respect for persons, beneficence, and justice. To operationalize these

principles, three methods were provided: informed consent, risk/benefit analysis, and the appropriate selection of subjects (Fischer, 2006).

The 1974 National Research Act, besides creating a national commission, established guidelines for research with human subjects. The concept of the Institutional Review Board (IRB) for research funded by the Department of Health, Education, and Welfare was introduced at that time. In 1991, these regulations were made applicable for 16 federal agencies and became known as the *Common Rule*, officially "Subpart A, Part 46: Protection of Human Subjects, of Title 45: Public Welfare," in the Code of Federal Regulations (45 CFR 46) (Fischer, 2006).

On January 15, 1994, President Clinton established the Advisory Committee on Human Radiation Experiments to investigate reports of unethical experiments funded by the U. S. government. The committee identified approximately 4,000 human radiation experiments sponsored by the federal government between 1944–1974 (McCarthy, 1998). These research studies all exhibited a variety of ethical issues including the use of vulnerable populations unable to give consent, failure to obtain consent, and the use of non-therapeutic treatments. Though I will not examine these studies here, they should be considered among the unethical studies performed in the U.S. Partly in response to the findings of this committee, The National Bioethics Advisory Commission was created by President Clinton in 1995. One of the first jobs of this commission was to advise the U.S. government on federal protections for vulnerable populations participating in research (McCarthy, 1998).

In the next subsection, I will examine the *Belmont Report* in detail. (See Appendix B for full text).

The *Belmont Report*. Introduced in 1979, the report is a result of hearings of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. It outlines three basic principles that direct the conduct of biomedical and behavioral research that utilizes human subjects: respect for persons,

beneficence, and justice. It also provides concepts that serve to guide researchers to adhere to these principles.

Respect for persons. The first ethical principle articulated in the *Belmont Report* (1979) is "Respect for Persons." The principle, further defined, stipulates that a person should have legal capacity to give consent, should be in a position to exercise free power of choice, and should have sufficient knowledge and comprehension of the study to make an informed decision. Respect for persons, contains two ethical tenets, the first being: "that individuals should be treated as autonomous agents" (Belmont Report, Part B, para. 2). This tenet reflects the first principle of the *Nuremberg Code*: "The voluntary consent of the human subject is absolutely essential"[7] ("The Nuremberg Code," 2005). The *Nuremberg Code* delineates what information should be disclosed to the subject, namely: the nature, duration, and purpose of the experiment, and the methods, risks, and possible effects to the subject. Commending this first principle of the *Nuremberg Code*, Katz (1992) remarks, "Never before in the history of human experimentation, and never since, has any code or any regulation of research declared in such relentless and uncompromising a fashion that the psychological integrity of research subjects must be protected absolutely" (p. 227).

The second tenet of respect for persons states "that persons with diminished autonomy are entitled to protection" (Belmont Report, Part B. 1., para. 1). In fact, some groups or individuals may be prohibited from participating in experimentation. Determining the extent of protection should depend on the level of risk and the likelihood of benefit (Part B, para. 5).

The *Belmont Report* lays out specific applications of the three general principles. To operationalize the principle of respect for persons, the participant is to "be given the opportunity to choose what shall or shall not happen to them" (Belmont Report, 1979,

[7] This section will use the term *subject* to reflect the language used in the *Belmont Report* rather than the preferred term *participant.*

Part C. 1, para. 1). This is done through the process of informed consent. The process of informed consent contains three elements:

1. Information: describes what sort of information should be provided. The items generally included are descriptions of the procedure, purposes, risks and benefits, and alternative procedures. Additionally, subjects are given the opportunity to ask questions and the opportunity to withdraw from the research.
2. Comprehension: includes issues of adaptating the information and allows special provisions for those who may have limited comprehension.
3. Voluntariness: includes issues of coercion.

Beneficence. The second principle of the *Belmont Report* is beneficence. Beneficence is an obligation. The two rules that define beneficence are: "1. do not harm and 2. maximize possible benefits and minimize possible harms" (Belmont Report, 1979, Part B. 2., para. 1). The researcher must ascertain when benefits can be pursued in spite of the risks and when benefits should not be pursued because of the risks. The *Belmont Report* notes that these obligations affect both the investigators and society. Once again, I hear an echo of the *Nuremberg Code* that declared, "The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment" ("The Nuremberg Code," 2005).

Just as informed consent is a tool used to operationalize the principle of autonomy, the assessment of risks and benefits assists in realizing the principle of beneficence. The *Belmont Report* stipulates that the term risk "refers to a possibility that harm may occur" (Belmont Report, 1979, Part C. 2., para. 2) and the term benefit "refers to something of positive value related to health or welfare" (Part C 2., para. 3). The balance that must be achieved is between the risk of harm to the research subjects and the foregoing of benefits resulting from the research. The *Belmont Report* instructs researchers and review boards to "consider alternatives systematically " (Part C. 2.,

para. 5), to look at the underlying assumptions of the research, and to consider whether the validity of the researcher's predictions of risks and benefits are reasonable. The *Belmont Report* lists five considerations to assess the justifiability of research (see Part C. 3. Selection of Subjects).

Justice. The third and final principle of the *Belmont Report* (1979) is that of justice. This involves issues regarding who is receiving the benefits of the research and who is bearing the burdens. The principle mentions several approaches to the distribution of benefits and burdens. The *Belmont Report* reviews the history of abuses in human subject research, cautioning researchers not to select subjects simply "because of their easy availability, their compromised position, or their manipulability" (Belmont Report, 1979, Part B. 3., para. 3). Therapeutic devices and procedures that are a result of research using public funds should be made available to all those who can benefit. Unlike the principles of respect for persons and beneficence, the *Nuremberg Code* does not directly discuss this principle as it is defined in the *Belmont Report*.

The principle of justice seeks expression in the careful consideration of who is selected to be subjected to the risks of research as well as who is included in possibly beneficial research. If the research does not contain a therapeutic component, researchers should choose subjects from classes of persons that are not already burdened by societal factors. Persons from vulnerable populations should be included in research only for justifiable reasons.

The next subsection will look at the friction that occurs over the issues of protection versus inclusion of minorities in human subject research.

Inclusion of minorities in human subject research. There is considerable literature looking at the low rates of minority participation in human subject research, including studies on what approaches might be best used to recruit these populations and studies on identifying and overcoming barriers to participation. This literature review will not go in depth on these topics, but rather will provide an introduction on why these

populations may be excluded, why they should be included, and the extent in which they are currently participating in human subject research. With respect to statistics and other forms of reported data, this review will focus on the Latino population.

Under the principle of justice the *Belmont Report* (1979) states,

> One special instance of injustice results from the involvement of vulnerable subjects…such as racial minorities…Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research…because they are easy to manipulate as a result of their…socioeconomic condition (Part C. 3., para. 5).

However, by excluding this population, they may be deprived of possible benefits resulting from participation in clinical research. These could include either therapeutic benefits resulting from direct research participation, or benefits to a specific group. Certain populations experience higher rates of particular conditions or diseases than the overall population, therefore inclusion of these populations is essential for generalizable research results. For example, among Hispanic adults (using an age-adjusted rate) diagnosed diabetes rates are 8.5% for Central and South Americans, 9.3% for Cubans, 13.9 % for Mexican Americans, and 14.8% for Puerto Ricans. In contrast, the rate among non-Hispanic whites is 7.6% (Centers for Disease Control and Prevention, 2014). Inclusion of minority members increases the generalizability of research results, while lack of participation contributes to health inequities and health disparities (Charleswill, 2014; Paskett, Katz, DeFraffinreid, & Tatum, 2003). Charleswill (2014) summarizes the importance of this situation: "The inclusion of minority populations in human subjects research may be a complex and challenging task; however, the consequences brought about by the gaps in data and information about the effects of therapeutics and other interventions on these groups are dire and of ethical importance" (p. 300).

Mastroianni and Kahn (2001) write about the balance between protection and access. The original intent of the principle of justice was to ensure "the fair distribution of the burdens and benefits of research in subject selection and recruitment" (p. 23). While at one time these vulnerable populations were excluded from human subject research in an effort to protect them from the possibility of the unethical treatment that had occurred in some past studies, eventually the position on inclusion was modified. Justice was now seen as access to potentially effective treatments, due in part by the insistence of certain communities to be included in research. Mastroianni and Kahn (2001) write, "the pendulum has swung from protection to access" (p. 21).

The term *vulnerabilty* has been interpreted in various ways, which can also be problematic. As seen in the section in the *Belmont Report* (Belmont Report, 1979, Part C.3. para.) and as discussed by Mastroianni and Kahn (2001), vulnerability falls under the principle of justice. Levine et al. (2004) feel the concept of vulnerability is both too broad and too narrow, "so many categories of people are now considered vulnerable that virtually all potential human subjects are included" (p. 46). There is also the possibility of harm to a participant who is fully capable of informed consent. They observe that, "the concept of vulnerability stereotypes whole categories of individuals" (p. 47). The authors conclude that special protections for an individual should not be based only on that person's membership to a particular group, but by also looking closely at the research project itself (Levine et al. 2004).

In an effort to increase inclusion of minorities, federal regulations such as Section 492B of the Public Health Service Act (42 U.S.C 289a-2), Inclusion of Women and Minorities in Clinical Research, have been instituted. This act states that researchers should include persons "in clinical research in a manner that is appropriate to the scientific question under study" (U. S. House of Representatives, Office of the Law Revision Counsel, United States Code, n.d.). However, Fischer and Kalbaugh (2011) acknowledge that "there are no databases aggregating demographic data from all clinical trials—neither those sponsored by the NIH nor those sponsored by the pharmaceutical

industry" (p. 2217). Fischer and Kalbaugh (2011) report statistics from one report that estimates Hispanics represent 7.6% of all NIH research participants (p. 2217). This percentage should be put in context with the fact that Hispanics represented 17% of the total U.S. population in 2013 (Brown & Patten, 2014)

While many acknowledge the importance of including minorities in clinical research, Fischer and Kalbaugh (2011) feel that this inclusion should be undertaken in a more mindful manner. They underscore the distinction of the various phases of clinical trial research and turn attention to which phases minorities may participate. Clinical trials often include three phases, though the number of phases can vary depending on what is being researched. For example, a Phase 4 trial may be conducted after the drug or treatment has been released.

Phase 1 trials are concerned with the safety of the treatment and often enroll healthy participants with the objective to determine proper dosages and adverse side effects. There are no direct benefits to the participants and the side effects are often unpleasant. Phase 2 trials are conducted with participants with the targeted disease. This phase is looking for data on how effective the treatment is and also looks at side effects and safety of the treatment. Phase 2 trials are approximately 50% effective (Fisher & Kalbough, 2011, p. 2217). Phase 3 trials also require participants with the targeted disease. This phase often uses randomized trial arms, with some participants receiving the treatment under investigation and others an approved treatment or a placebo. These trials have the potential to provide the greatest benefits to the participants and have an 80% success rate (Fisher & Kalbough, 2011, p. 2217).

What Fischer and Kalbaugh (2011) are concerned about, though there are no firm statistics, is that members of minority communities may be participating in Phase 1 studies in greater number than their representation in the overall population and are underrepresented in Phase 3 studies. There is less benefit to the participants in Phase 1 studies and a fairly large burden of risk. While it is not clear why this might occur,

Fischer and Kalbaugh (2011) suspect lack of access to care and monetary remuneration may play roles. To better understand how a participant is enrolled in a clinical trial, I next look at informed consent in some depth.

Examining informed consent. Thinking through the nature of consent (consent generally, not only in biomedical research), philosopher John Kleinig provides a grammar of consent asking: "What needs to be true of *A*, *B*, and ℓ, if it is to be justifiably said that '*A* consented (to *B*) to ℓ'?" (2010, p.5). Requirements for *A* include being an agent with "a certain level of maturity" (Kleinig, 2010, p. 5); requirements for *B* include being the one who "initiates the process of inquiry to which *A*'s permission to do something is sought" (Kleinig, 2010, p. 6). This is something that prior to the consent *B* had no moral right; ℓ is a course of action that *B* has no moral right to without *A*'s consent. Importantly, Kleinig (2010) notes that consent is a social act and a communicative act that must be signified and recognized. This grammar of consent is useful in examining specific instances of consent. I will now move onto looking at informed consent as it is used in biomedical research with human participants.

Research using human participants requires a higher standard of informed consent than that required for clinical care due to the uncertain nature of research and a potentially higher burden of risk. Because of this it is highly regulated. However, as Siminoff (2003) notes, " a standard bioethics principal-based framework does not provide guidance as to how the process of informed consent should be operationalized. Nor does such a framework allow the process to be tailored to various patient/subject populations" (p. S2). As a result, conventional topics presented in a conventional manner may not be understood by all potential research participants. This subsection will provide a sampling of the empirical research that has been done to investigate various aspects of the informed consent process in the human subject research setting including: empirical research on informed consent research, the amount and type of information presented, modifications of the consent form, participant comprehension, modification of the consent process, participant recall, and the effects of ethnicity and culture.

This subsection contains several studies that included Latino participants. It is important to note that these studies were purposefully sought and included in this review of literature. As shown in the previous subsection, members of the Latino community are underrepresented in clinical trials; they are equally underrepresented in research on informed consent. Thorough literature searches exemplify the paucity of studies that have included this population. The studies by Lakes et al. (2011) and Cortés, Drainoni, Henault, and Paasche-Orlow (2010) are the two studies most closely resembling the research presented in this dissertation; with Cortés, Drainoni, Hanault, and Paasche-Orlow (2010) being the only study located whose only participants are Spanish-speaking persons.

As mentioned in the subsection, "Evolution of the legal doctrine of informed consent—landmark cases," Beauchamp (2011) has identified two different meanings of informed consent. The first meaning deals with autonomous authorization where "[a] person gives an informed consent… if and only if the person, with substantial understanding and in substantial absence of control by others, intentionally authorizes a health professional to do something" (p. 518). The second meaning "refers only to a legally or institutionally effective approval given by a patient or subject" (Beauchamp, 2011, p. 518). Informed consent as described in the *Belmont Report* (Belmont Report, 1979, Part C.) is intended to achieve the first meaning, one focused on autonomous choice. Beauchamp (2011) defines consent around autonomous choice: "An informed consent occurs if and only if a patient or subject, with substantial understanding, and in the absence of substantial control by others, intentionally authorizes a professional to do something" (p. 57). Researchers who apply only institutional rules risk obtaining a consent that is not autonomous.

Sachs et al. (2003) looked at the challenges in conducting empirical research on informed consent. These challenges include study design issues, difficulty obtaining IRB approval, and issues related to the difficulty of consent researchers obtaining access to trial participants. They note that those who want to study informed consent must rely on

the cooperation of the clinical researchers, which often limits access for consent researchers.

I next examine a sampling of studies that investigate various aspects of informed consent, both the form and the process. The studies are arranged under the three applications of the general principle of respect for persons: information (disclosure), comprehension, and voluntariness.

Information (disclosure). The amount and type of information provided to a potential participant is subject to debate. The *Belmont Report* does allow that, "a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided" (Belmont Report, 1979, Part C. 1., para. 3).

Edwards, Lilford, Thornton, and Hewison (1998) conducted a literature review on different methods of obtaining informed consent for enrollment into clinical trials. The results of these various studies suggest that providing more information and time to consider that information resulted in lower consent rates. However, in general, more information resulted in greater understanding of the topic of the trial and the research nature of the treatments, alternative treatments, and voluntariness. The literature was contradictory on the topic of randomization. The authors conclude that since autonomy is the grounding of informed consent, "a patient [being enrolled in a clinical trial] should be asked whether or not they wish any information upon which to base a decision" (p. 1839).

This interesting proposal, for the participant to determine the amount of information given to them, is echoed in a more nuanced manner by Epstein, Korones, and Quill (2010). Though they are speaking of consent in clinical settings, their views are relevant for patients enrolling in trials. The authors are, in effect, attempting to balance autonomy, beneficence, and nonmaleficence by giving an individual a choice on providing or withholding information. Too much information, they explain, can create a

cognitive overload potentially interfering with understanding and decision making. O'Neill (2003), in a discussion of limitations of informed consent, also looks at the amount of information disclosed. "The inclusion of excessive or technical detail…will eventually overtax even the most energetic, and undermine the possibility of informed consent. On the other hand, consent that is too vague and general may also fail to legitimate action" (p. 5).

It is the enroller who controls the amount of information disclosed, providing possibly too much information as discussed in the previous paragraph, or allowing for the possibility of selective disclosure to different groups of people. Simon et al. (2003) examined consent for participation in randomized clinical trials for childhood leukemia. Using a social position instrument, it was found that the non-English speaking group of parents (all but one person in this group was Spanish-speaking) had a lower social status score that included a statistically lower educational level than the English-speaking group. The findings show that enrollers omitted certain information such as that related to randomization, the right to withdraw, and consent documentation in their discussions with non-English speaking parents. The other significant finding was that non-English speaking parents had difficulties grasping certain features of the consent such as randomization, the differences between the clinical trial and standard treatment, voluntariness, and the right to withdraw from the trial. Interestingly, enrollers spent roughly the same amount of time with non-English speaking parents as with the other groups suggesting they may be adhering to a specified amount of time for the conference, regardless of the time necessary to ensure proper disclosure and comprehension. Also observed, non-English speaking parents asked fewer questions than English speakers, perhaps because time did not allow for discussion.

Simon and Kodish (2005) look at the effects of ethnicity and culture on informed consent in pediatric cancer clinical trials and found statistically significant differences in the information content provided to Caucasian group members versus the minority parents, including the right to withdraw and the risks and benefits. They acknowledge

Faden and Beauchamp's observation that "in the past, minorities often were not granted access to the potential benefits of medical research participation, or else were unethically recruited and subjected to harmful tests without their full knowledge and consent" (as cited in Simon & Kodish, 2005, p. S131). They also observe, "Rather than trying to learn about the multiple beliefs and customs of particular groups of people—an almost impossible task—I ought to listen and talk to people about their shared needs and preferences" (p. S134). Simon and Kodish (2005) advise researchers to be aware of certain characteristics of a group, such as the Latino belief in *fatalismo* and the value of *respeto* (both terms are discussed further in the section Intercultural Communication—Latino Culture).

Comprehension. Wendler (2004) reminds us that the gap between having the capacity to give consent and giving valid consent is often the result of not understanding one or more aspects of the disclosed information of the informed consent process. The principle of comprehension allows for adaptations of the information, including modifications of both the form and the process. Siminoff (2003) tells us that the literature is consistent, gaps in recall or understanding of pertinent information can be caused by consent forms that are often "dense and confusing" (p. S2). The *Belmont Report* stipulates that "Investigators are responsible for ascertaining that the subject has comprehended the information" (Belmont Report, 1979, Part C. 1., para. 7). However, the *Belmont Report* does not give much guidance on how to do this. It does mention cases where the presentation of the information should be adapted. Such cases include "conditions of immaturity or mental disability" (Part C. 1., para. 8).

One well-studied aspect is the readability of the information. Paasche-Orlow, Taylor, and Brancati (2003) investigated the readability standards for informed consent forms using the Flesch-Kincaid readability scale. Results demonstrated a mean Flesch-Kincaid grade level of 10.6. Only 8% of the IRB-supplied forms met their own stated standards, with the mean score for readability exceeding the IRB's stated standards by 2.8 grade levels. The authors note that other factors such as "type font, layout, and

length" (p. 725) all affect readability and suggest using text written at a fourth-grade level to increase the autonomy of most potential participants.

Another readability study by Tait, Voepel-Lewis, Malviya, and Philipson (2005), tested a standard consent document modified to meet federal guidelines for readability and processability against a standard consent form. To do this the standard forms were analyzed to determine their actual readability and processability. They were then modified to an eighth grade reading level and to a processability score of approximately 70. This included attending to formatting such as the use of boldface fonts, underlining, bullet lists, and pictographs. The participant's perceptions of their understanding of the information was high, however their actual understanding, when assessed by the researchers, was quite a bit lower than their perceptions.

While there were no differences in the participants' satisfaction with the consent process using either the standard or modified form, there were differences in understanding. The modified form resulted in greater understanding among participants with an eighth-grade reading ability or lower. Participants using the standard consent form identified the risks of the trial to be significantly lower than the participants using the modified consent form. Of all participants, 81.2% preferred the modified form, however those who preferred the standard form felt it was 'more professional,' 'shorter in length,' and 'more serious' (Tait, Voepel-Lewis, Malviya, & Philipson, 2005, p. 351). This suggests that following the federal guidelines on readability and processability will result in greater understanding.

In contrast, Stunkel et al. (2010) looked at the effect of a "shorter and simpler consent form on the comprehension and satisfaction of research participants" (p. 1). Their findings showed no correlation between the length and the complexity of the form with respect to comprehension or satisfaction. The only variable associated with lower comprehension was a lower education level. This finding would suggest that reading level is the important variable.

Confirming the positive interaction between education and reading level and understanding, Flory and Emanuel (2004) reviewed various interventions employed to improve understanding of the information disclosed in an informed consent process. The interventions included "(1) multimedia, (2) enhanced consent form, (3) extended discussion, (4) test/feedback, (5) miscellaneous" (p. 1594). All of these adaptations reported limited success, however there was some evidence that the extended discussions showed promise of improving understanding. The study did reveal higher education or reading level correlated with higher understanding scores, while sex and minority status did not show an effect.

To address the issue of a lower education status and understanding, Sudor et al. (2006) investigated whether literacy and other demographic characteristics were associated with an understanding of a modified consent process. This process included a consent form written at a sixth-grade level, read to the participants, followed by seven questions combined with targeted education. Results showed that with repeated teach-to-goal passes, 98% of the participants eventually achieved understanding. Those with lower literacy and minority status showed the greatest risk for poor understanding.

Various instruments have been developed to assist in comprehension. Cortés, Drainoni, Henault, and Paasche-Orlow (2010) sought to test and refine the *Informed Consent and Authorization Toolkit for Minimal Risk Research*. This toolkit was developed by the Agency for Healthcare Research and Quality to facilitate the process of obtaining informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization from potential research subjects. The documents used plain language, were written for persons with low literacy, and were translated into Spanish since participants were Spanish-speaking. Results included participant's negative response to the length of the documents. The mandatory reporting status of the researchers caused some participants to consider not participating.

Education level may also be a predictor of information recall. Griffin et al. (2006) conducted exit interviews with participants in a five-year clinical trial. They asked the participants to recall the study's purpose, the name of the medication under investigation, and the main side effect of the medication. Those with incorrect answers included older participants, those with the least education, and Black and non-white participants, who made up only 8.4% of total trial participants.

Agre et al. (2003) looked at eight studies that examined various interventions looking to improve either decision-making, knowledge, or the therapeutic misconception. One of these studies by Agre and Rapkin, looked at using various media: standard consent, video, computer program, and booklet. Better scores were correlated with the complexity of the protocol and those with more education. Lower scores were correlated with minority status and those in poor health. Specifically, the medium of video was superior to the computer for complex protocols and for minority participants. The booklet format was better for those in poor health, though worse for minorities. This suggests that reading levels may be an issue for minorities. Another study by Kass et al. (as cited in Agre, 2003) assessed the effects of a narrated, self-paced, touch screen computer-based intervention (developed after observing oncologists inviting patients to participate in a clinical trial). Those in the computer group said "the information changed the way they made their decisions" more than those in the pamphlet group (p. S14). The authors conclude that none of these eight intervention studies found satisfactory ways to increase information transfer, satisfaction with decisions, or to affect decision making. Kass et al. note they "may need to modify [their] analytic approach. Manipulating the communication technique may be less important than looking more carefully at information processes" (p. S19).

The concept of randomization has shown to be problematic for participants of all demographics. However, it may be particularly troublesome for Spanish-speaking members of the Latino community. Kodish et al. (2004) studied the explanation and understanding of the concept of randomization with parents of children being recruited

for a childhood leukemia trial. 44% of the participants were a minority, predominately Latino. Of the 137 participant's conferences, 111 were conducted in English, 24 included interpreters, and two were conducted in Spanish. Results indicated 50% of the parents did not understand the concept of randomization, and with racial minorities and those with a lower socioeconomic status less likely to understand. The authors suggest tailored interventions for these parents saying, "Future research must identify the source of the gap between explanation and understanding, with special attention to barriers noted in parents of racial minority and lower SES" (Kodish et al., 2004, p. 475).

Finally, considering the effects of ethnicity and culture, Quinn et al. (2012) note that participation by members of racial and ethnic minorities is underrepresented in biomedical and clinical research. Importantly they reconsider describing the decision to participate as an individual decision. "In some communities, where the family or community is an integral part of the decision-making process, and risks and benefits of research participation are considered in terms of how the larger group will be affected, investigators should allow enough time for participants to engage in relevant group decision-making process" (p. 2). The results of this research suggest comprehension can be improved by attending to methods preferred by the community.

Voluntariness. Voluntariness is sometimes equated with autonomy. I adopt the stance provided by Beauchamp and Childress (2009) that holds that "a person acts voluntarily if he or she wills the action without being under the control of another person or condition" (p. 138). The authors identify three categories or forms of influence:

- Coercion: Beauchamp and Childress state that coercion "occurs if and only if one person intentionally uses a credible and severe threat of harm or force to control another" (p. 138).
- Persuasion: Persuasion is defined as influence by appeal to reason, distinct from an appeal to emotion, in which a person accepts the notion the persuasive individual is putting forward. Faden and Beauchamp (1986)

say “persuasion is never controlling and involves no degree of noncontrol” (p. 258).

- Manipulation: This form of influence is not persuasive or coercive. Forms of manipulation may include, for example, “lying, withholding information, and misleading by exaggeration with the intent to lead persons to believe what is false” (p. 139).

Voluntariness is the least investigated application of informed consent. Looking to understand how persons make the decision to participate or not participate in clinical research, Lakes et al. (2012) asked participants from diverse backgrounds about their reactions when considering participation in research in an attempt to “describe the experiences, perceptions, attitudes and values” that are part of this decision making process (p. 218). The results were reported as themes including concerns of undocumented immigrant people, perceived risks of participation, and decision-making strategies. Closely involved with participation in research are issues of autonomy, which I will examine in detail in the next subsection.

Autonomy. Felt, Bister, Strassnig, and Wagner (2009) challenge the current understanding of autonomy. They suggest that the “bioethical ideal” of providing comprehensive information to aid an individual in decision making is incomplete. They feel that individuals make decisions on clinical interventions or on participation in clinical trials based on information from sources other than the information presented to them by the physician or researcher. “The framing of autonomy as informed choice that presents a narrow set of ready-made options for patients is seen as insufficient for describing and taking into account the complexities of social and historical context that contribute to patients’ ways of dealing with medical encounters” (Felt et al., 2009, p. 4). The authors suggest there exists a discrepancy between the “bioethical ideal” and the practice of informed consent. They found that patients may not be directly attending to information presented in the informed consent process and instead relying on personal experiences, perceptions, and “imaginations” to make their decisions (Felt et al., 2009).

This study opens a space to consider how individuals understand and exercise autonomy within the process of informed consent as well as to consider what level of autonomy is actually available to an individual.

Throughout this literature review I assume the potential participants are competent to make an autonomous decision, meaning they have the ability to perform a task with the reminder that the criteria of competency is relative to the task. In other words, a person may be competent to make a decision in one area and not in another.

I next introduce a theory of autonomy, acknowledging that various authors assign various meanings to the term autonomy. This subsection first considers the definitions and discussions provided by Beauchamp and Childress (2009) and recognize this view as dominant in the field, followed by views of autonomy provided by other scholars and theorists who disagree with the views of Beauchamp and Childress, to varying degrees. Beauchamp and Childress (2009) explain, "at a minimum, personal autonomy encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as inadequate understanding" (p. 101). Theories of autonomy include the conditions of liberty and agency as vital.[8]

Beauchamp and Childress (2009) have put forth a three-condition theory that focuses on non-ideal conditions. This theory assumes the persons are competent and describes the following conditions:

- Intentionality: This refers to an intentional action that comes about as a result of a plan. "Acts are either intentional or nonintentional" (p. 102)
- Understanding: Autonomous action can be considered on a continuum, and does not require complete understanding, "To restrict adequate decision making by …research subjects to the ideal of fully or completely autonomous decision making strips their acts of any meaningful place in

[8] This review does not include discussion of implicit (or implied) consent or presumed consent.

the practical world, where people's actions are rarely, if ever, fully autonomous" (p. 104). The level of understanding corresponds with the quality of the autonomous decision.

- Non-control: This condition requires that an individual is not controlled by external sources. It also includes control by internal sources "that rob the person of self-directedness" (p. 104), for example mental illness.

An act can be autonomous by degrees, explain Beauchamp and Childress (2009), existing on a continuum of both understanding and non-control and is best considered in the context of a specific decision. The principle of respect for autonomy should acknowledge "the value and decision-making rights of autonomous persons and [enable] them to act autonomously" (p. 107) as opposed to a disrespect for autonomy, which would "ignore, insult, demean, or [be] inattentive to others' rights of autonomous action" (p. 107).

Walker (2009) challenges Beauchamp's and Childress's views on autonomy. She summarizes their representation of nonautonomous actions as meeting one of three conditions: that they be unintentional, lacking understanding, or controlled internally or externally. Walker (2009) charges that this viewpoint "fails to properly identify nonautonomous actions and choices, it gives a false account of which features of actions and choices make them nonautonomous, and it provides no grounds for the moral requirement to respect autonomy"(p. 595). Specifically, it does not address three possible ways a person's action can nonautonomous: by demonstrating a "faltering self-rule" or weakness of will, by making a choice that does not represent a person's authentic self, or by making an irrational choice. Considering the principle of respect for autonomy, Walker (2009) makes a distinction between "respect" for a person's choices and "abiding" by those choices; " [a]lthough one of the ways I show respect for a person is to abide by her choices, I need not thereby respect her nonautonomous choices (even if I must abide by them)" (p. 606).

Considering the various moral theories behind the concept of respect for autonomy, Walker (2009) agrees with O'Neill's (2003) claim, that while the principle of respect for autonomy is often said to be influenced by Kant (though this is not necessarily put forward by Beauchamp and Childress), it does not correctly reflect Kant's actual conception of autonomy: "it is impossible to see how a view of autonomy that does not even require that choices and actions be rational could be "Kantian" much less Kant's" (p. 603).[9]

Warren (1989) looks at ethics from a feminist perspective. She makes this important observation: "Which questions moral philosophers choose to study—and choose not to study—is itself a moral issue, yet one that is hardly ever raised" (p. 76).[10] She provides an interesting distinction between what she terms as "housekeeping issues" (these are personal issues) and "crises issues" (these are 'big' issues such as the withdrawal of life-support). What if, she asks, informed consent is viewed as a "housekeeping issue"? She illustrates this by asking the question, "How should I foster the conditions which make informed consent more likely?" (p. 79). This question urges reevaluating the relationship between researcher and potential subject.[11] Warren then poses a potential solution to help overcome issues of power. She suggests that physicians (in this case I am thinking about researchers) consider themselves educators rather than authorities. "Teachers need to repeat, to connect with *this* student's experience, and to get feedback from students so that inaccuracies can be corrected" (Warren, 1989, p. 82).

Sherwin (1998) also uses a feminist perspective to offer an alternative view of autonomy, a relational approach that "allows us to maintain a central place for autonomy within bioethics, but…requires an interpretation that is both deeper and more complicated

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[9] For an account of Kantian philosopher Onora O'Neill thoughts on autonomy see: O'Neill, O. (2003), "Autonomy: The Emperor's New Clothes." *Aristotelian Society Supplementary Volume*, *77*(1), pp.21–21.

[10] Warren refers predominately to woman in her article. I am choosing to follow Sherwin (1998) by including minorities and other disenfranchised populations within the focus of feminist study.

[11] See Appendix D for a reflexivity discussion regarding my position as a researcher in relation to this study's participants.

than the traditional conception acknowledges" (p. 44). This approach can be thought of as 'socially situated' or 'contextualized.'

Sherwin (1998) explores problems with the principle of autonomy as it is commonly interpreted. Informed consent does not ensure patient autonomy; this is especially true when considering diverse, urban communities. In fact, persons experiencing oppression may be restricted to a point that "it is distorting to describe as autonomous some specific choices made under such conditions" (pp. 27-28). She observes that health care providers do not necessarily have the communication skills to ensure patients have the understanding to provide informed consent. "This problem is compounded within our increasingly diverse urban communities where differences in language and culture between health care providers and the patients they serve may create enormous practical barriers to informed choice" (Sherwin, 1998, p. 24).

It is problematic when an individual is isolated from the context that might be producing the problem or condition. Feminism offers a perspective to think about how issues involve power, dominance, and privilege. Sherwin (1998) proposes a relational alternative. "A relational conception of personhood …recognizes the importance of social forces in shaping each person's identity, development, and aspirations" (p. 35). The implications of this relational interpretation of autonomy for health care includes understanding informed consent as an ongoing process and one that requires an interpretation that is more complex than the traditional conception of consent.

McLeod and Sherwin (2000) extends the discussion of relational autonomy by focusing on how oppression obstructs autonomy; it "functions in complex and often largely invisible ways, affecting whole social groups rather than simply disrupting isolated individuals; as a result, its effects tend to be ignored within the traditional autonomy framework that focuses solely on individuals" (p. 259). The authors nuance the effects of oppression by noting that individual members of oppressed groups are affected in individual degrees and, by belonging to more than one group (e.g., minority,

gender, education level), an individual may be privileged in some areas, while oppressed in others. Notably, they remind us that those experiencing oppression are not necessarily incapable of exercising autonomy and conversely those belonging to a dominant group are not necessarily capable of exercising autonomy.

McLeod and Sherwin (2000) also explore the effect oppression has on a person's self-trust and argue that a degree of self-trust is a necessary prerequisite of autonomy, saying "[an][a]gent must trust her capacity to make appropriate choices, given her beliefs, desires, and values; that she trust her ability to act on her decisions; and also that she trust the judgments she makes that underlie those decisions" (p. 263). Finally, they observe that medical settings, similar to oppression, involve unequitable distributions of power. Sherwin (1998) points to the strength of the principle of autonomy, "A principle insisting on protection of patient autonomy can be an important corrective to such overwhelming power imbalances" (p. 22). However, she also acknowledges that determining how a power imbalance interferes with autonomy is not well understood.

Dodds (2000) acknowledges Sherwin's feminist approach to autonomy includes the incorporation of social relations and includes an understandable account of oppression. However, Dodds veers from Shewin's relational autonomy notion in that she feels problems with the principlist notion of autonomy are not only oppression or gender. Dodds (2000) argues that "respect for autonomy is not restricted to respect for choices of a certain kind but also requires promotion of the development of autonomous selves" (p. 227). She adopts Meyers' concept of autonomy competency in order to extend Sherwin's approach. In exercising one's autonomy, Meyers writes about the presentation and amount of information given in the informed consent process saying the focus should be on "the development and exercise of people's autonomy competency" (Dodds, 2000, p. 231). Providing large amounts of information does not protect autonomy. It may be better to provide counseling to assist the individual in determining "what it is he or she really wants in the context…[and] may better promote autonomy than greater information" (p. 231). Dodds (2000) also suggests that a person may gain a greater

understanding of a specific treatment or condition by meeting with survivors or caregivers.

Gillies and Entwistle (2012), in their discussion of relational autonomy agree that supportive communication can be considered as respectful of personal autonomy. They explain, "Relational understandings highlight the potential value of some professional intervention as supportive of the development and exercise of autonomy by individual patients…[I] encourage nuanced and context sensitive explorations of the appropriateness of various forms of communication" (p. 753). The authors suggest an adoption of, what they term, an invitation/request approach to communication that attempts to avoid overburdening individuals with unwanted information while still providing the appropriate trial information. I next explore how the discipline of rhetoric can help illuminate and analyze the process of informed consent.

Rhetoric

Rhetoric, both classical and contemporary, provides important methods to analyze and construct scientific and medical discourse. Science can be thought of as a collection of communicated knowledge—as a group of practices that needs to be persuasive if it is to be believed. Lyne (2001) observes, "Biomedicine, whether considered as a science or as a context of ethical concern, is …rhetorically contoured as discourse that persuades or fails to persuade its various audiences" (p. 4).

Contemporary rhetoric. It is important to note that the while the humanistic tradition locates the art of rhetoric in the public sphere, it specifically excluded the technical and theoretical sciences as loci for rhetoric. Contemporary rhetoric has chosen to overlook this distinction (Leff, 1987). There are a number of concepts in both classical and contemporary rhetorical theory that may prove useful in analyzing the informed consent conference, both the textual and the oral components. Segal (2005) observes, "What frequently is thought of as 'informed,' 'shared,' or even 'consensual' decision

making is actually when considered rhetorically a process of persuasion in which the parties are not, despite appearances, fully rhetorical partners" (p. 94).

Kenneth Burke (1969) observes that language is "a symbolic means of inducing cooperation in beings that by nature respond to symbols" (p. 43). My project looks to examine whether the 'symbols' being used are concordant with the social and cultural needs of the audience. Burke's concept of *identification* is useful to examine this concordance. Sharing substances, be they physical objects or beliefs, allows one to be *consubstantial* with another. The symbols used for identification are varied, described by Burke in this way, "You persuade a man only insofar as you can talk his language by speech, gesture, tonality, order, image, attitude, idea, *identifying* your ways with his" (Burke, 1969, p. 55). An audience is more likely to be persuaded if the speaker identifies with the audience, a least at the intersection of their joint interests.

Another Burkeian concept of use for rhetorical analysis in this project is that of *terministic* screens. Burke tells us there are two types of terministic screens, a *scientistic* approach and a *dramatistic* approach. The scientistic approach defines a word in terms of " it is or it is not" (Burke,1966, p. 45). In this approach, word choice defines the reality. The dramatistic approach is focused on action, "thou shalt or thou shalt not" (Burke, 1966, p. 45). In this approach, word choice influences people to act in a certain way. Burke says, "We must use terministic screens, since we can't say anything without the use of the term; whatever terms we use, they necessarily constitute a corresponding kind of screen; and any such screen necessarily directs the attention to one field rather than another" (Burke,1966, p. 50).

Additionally, contemporary rhetorical theory is useful in interpreting and clarifying the problems that arise when a researcher is not connecting with the research participant, not achieving the 'bioethical ideal' of informed consent that Felt, Bister, Strassnig, and Wagner are describing. Chaim Perelman and Lucie Olbrecths-Tyteca (1991), in their book *The New Rhetoric*, rethink the Aristotelian notion of persuasion.

They introduce a Theory of Argumentation: "the object of the theory of argumentation is the study of the discursive techniques allowing us *to induce* or *to increase the mind's adherence to the theses presented for its assent*" (p. 4). What I am arguing in this project is that informed consent is a form of persuasion; a form of argumentation and for *ethical* persuasion to take place, the researcher needs to fully understand the needs and values of the research participants. What needs to be achieved is what Perelman and Olbrecths-Tyteca term a "contact of minds." They explain, "The indispensable minimum for argumentation appears to be the existence of a common language, of a technique allowing communication to take place" (Perelman & Olbrecths-Tyteca, 1991, p. 15).

Segal (2005) makes an observation that ties this notion of a "contact of minds" to the process of informed consent: "Chaim Perelman and Lucie Olbrecths-Tyteca say the conditions for rhetoric include conditions for 'a contact of minds', and if these conditions are not met, then the people addressed do not properly constitute a rhetorical audience, and what is going on is not really *rhetoric* at all but something else: coercion, perhaps" (p. 91). This is the ethical implication.

Classical rhetoric. Aristotle's artistic proof *êthos* is also important to this project. The first passage of interest is in *Rhetoric* (Book 1 1.2) where Aristotle, after defining rhetoric, describes two forms of proof (*pisteis*), artistic (*atechnic*) and inartistic (*entechnic*). Of the inartistic proofs, those provided through speech, Aristotle describes three species: *êthos*, *pathos*, and *logos*. To Aristotle, the term *êthos* refers to the speaker's moral character as demonstrated through his speech.

Aristotle further discusses *êthos* in *Rhetoric* 2 1 "for it makes much difference in regard to persuasion (especially in deliberations but also in trials) that the speaker seem to be a certain kind of person and that his hearers suppose him to be disposed toward them in a certain way and in addition if they, too, happen to be disposed in a certain way [favorably or unfavorably to him]" (*Rhetoric* Book 2 1.3). Aristotle then gives very specific reasons why speakers are persuasive: "There are three reasons why speakers

themselves are persuasive; for there are three things I trust other than logical demonstration. These are practical wisdom [*phronêsis*] and virtue [*arête*] and goodwill [*eunoia*] for speakers make mistakes in what they say through [failure to exhibit] either all or one of these" (*Rhetoric*, Book 2 1.5). I will not discuss practical wisdom, virtue or goodwill here, but all may have a place in the analysis.

Interestingly, Grimaldi (1990) takes a wide and unconventional view of *êthos*. He argues that the meaning of *êthos* as an entechnic *pistis* extends to the *êthos* of the audience. The speaker must be aware and familiar with the *êthos* of the audience and he must use that *êthos* in the construction of his message. The speaker "must attend to and adjust himself to the type of auditors addressed if he is to address them successfully" (p. 73). Grimaldi points to passages Book 2 12–17 in Aristotle's *Rhetoric* as the place where Aristotle addresses the *êthos* of the auditors. Adopting Grimaldi's approach to *êthos* by extending the consideration to the audience would allow a place for the speaker to reflect the culture in their message by exhibiting membership in the community by reflecting similar values and beliefs.

It should be noted that there are several aspects of persuasive communication that Aristotle does not address or does not allow. He makes it clear that the reputation of the speaker is not to be considered in persuasion through character. "[There is persuasion] through character whenever the speech is spoken in such a way as to make the speaker worthy of credence; for I believe fair-minded people to a greater extent and more quickly [than I do others], on all subjects in general and completely so in cases where there is not exact knowledge but room for doubt. *And this should result from the speech, not from a previous opinion that the speaker is a certain kind of person* [emphasis added]" (*Rhetoric*, Book 1 2.4).

When exploring Aristotle's theories on persuasion through character, I attempted to limit the discussion, where possible, to deliberative rhetoric. This is not possible when looking to the Roman rhetoricians, as the majority of their discussions relate to judicial

rhetoric. It is necessary to keep this in mind since the persuasion described by Cicero and Quintilian is focused on winning a judgment and defeating an opponent. There is not a complete analogy to the intercultural informed consent I am looking to illuminate. Nevertheless, Cicero and Quintilian's theories are very valuable to my current project.

Cicero did not adopt Aristotle's concept of *êthos* and *pathos*. Antonius, speaking in *De Oratore*, describes Cicero's approach, "My oratorical method, and the skill that Crassus praised to the skies just now are, as I said before, based entirely on three procedures: one is to win people over, the second, to instruct them, the third, to stir their feelings—the first of these elements requires that you speak with gentleness, the second with intellectual acumen, and the third with vigor" (Cicero *De Oratore*, Book II.128-129, May & Wisse). Cicero combined Aristotle's concepts of *êthos* and *pathos* into his own account of the use of emotions.

Quintilian translated *pathos* directly as "emotion" (*adfectus*). However, he did not feel there was an adequate Latin translation for the Greek word and concept of *êthos*. He noted that the term *mores* was often used. Quintilian did not feel this term completely captured the concept. He felt *êthos* was to be treated as a "special aspect" of *mores*. He explained that "more cautious writers"—perhaps he was thinking of Cicero—had chosen to explain the sense of the word rather than translate it. He went on to say that these authors described some emotions as violent and others as gentle and steady; violent emotions command and gentle emotions persuade. The gentle emotions could also be considered as agents of goodwill. Quintilian also notes some writers have called *êthos* permanent and *pathos* temporary (Quintilian, *Institutio Oratorio* 6.2).

In addition to providing instruction on how to persuade using the emotions, both Cicero and Quintilian allow the reputation of the speaker to be considered as part of his character, adding to the persuasiveness of the speech. In Quintilian's time, familial authority carried much weight. "good birth is rank in society that derives from ancestors" (2.15.2). In the teachings of the Romans, allowances provide for the inclusion of

nonverbal and paraverbal communication (e.g., tone, pitch, volume, pacing), recognition of reputation, and a wider use of emotions in persuasion. Additionally, the importance of wearing the proper attire to signify rank and status also demonstrates the fact that the reputation of an individual was held in high regard. This moves well beyond Aristotle's use of the concept of *êthos*. Though I will not provide a detailed analysis of Aristotle's system of epideictic rhetoric, I want to acknowledge the possible role this system can play in this project. Classical epideictic rhetoric involves praising an individual, group, or event in order to display a group's shared values. Fahnestock (1998) explains the use of epideictic rhetoric in science journalism, explaining that epideictic rhetoric adjusts the science information to the values and assumptions of the non-scientific audience. Sullivan (1991) tells us, "If science is indeed a culture, then it should be possible to characterize internal scientific discourse in terms of epideictic theory because historically, epideictic rhetoric has been the genre understood to create and to maintain a society's value system" (p. 229).

Scientific and Technical Communication

Scientific and technical communication is a field grounded in rhetorical theory and is concerned with the gathering, organizing and transferring of technical information to a specific audience through a variety of media. It is a field well-suited to rhetorically address matters of medicine, health, and bioethics. Technical communicators, like bioethicists, must approach their work thoughtfully and ethically. Callahan defines bioethics as "the application of ethical theory to the dilemmas raised by the practice of modern medicine, especially those problems raised by the applications of new technologies" (as cited in Hedgecoe, 2004, p. 122). Successful technical communication accomplishes the task of communicating formalized discourse, in this case trial and consent information, in a manner that allows the audience to have the necessary knowledge to make decisions and perform actions. In this section, I briefly touch on the topics of technical communication ethics, critical research, participatory research, the role of feminism, risk communication, and localization.

Dombrowski's *Ethics in Technical Communication* (2000), was one of the first book-length treatments on ethics specifically focusing on technical communication. Porter (1993) is critical of Dombrowski's use of large-scale cases (e.g., the *Challenger* Disaster, Nazi records) and maintains that such large-scale cases, often involving whistle-blowing, are not particularly useful to illustrate ethics because they imply that such incidents are extremely rare, therefore technical communicators do not need to attend to ethics on a daily basis. Though ethics is of course an integral part of the field of technical communication, scholarship on the topic is rather sparse.

Critical research approaches can work to illuminate ethical issues in technical communication. The informed consent conference uses a variety of documents, which, it could be argued, serve more of a utilitarian purpose than serving the ethical ideal of informed consent. Borrowing concepts from work with critical research in technical communication by Blyler (1998) and Thralls and Blyer (2002) may work to illuminate issues in the conference involving relations of power. A goal of the critical perspective is empowerment and one way to accomplish this is to reconsider the relationship between the researcher and the research participants. Critical researchers think of this relationship as a collaboration. In this way, critical researchers advocate forms of participatory research.

Participatory research can be thought of in terms of audience. Johnson (2004) notes "the audience has been marginalized by a preponderance of scholarship that hegemonically places the receivers of discourse literally at a distance" (p. 93). Johnson, referring to Ede and Lundsford, tells us this situation is referred to as audience invoked. This is distinctly different than classical rhetoric, where the audience was fore fronted for the purpose of being informed, persuaded, or entertained, a situation which Johnson, again referring to Ede and Lunsford, calls audience addressed. He then introduces his

concept, which he calls audience involved (Johnson, 2004). This is the view of participatory research I will be discussing in this project.[12]

Participatory research lends itself to the use of the feminist perspective. Lay (2002) reminds us that feminism is a perspective, not a research method. The researcher might employ the feminist perspective in methodologies "such as case studies, textual analysis, interviewing, and ethnography" (p. 169). Among the guidelines Lay references is the goal to "make visible those lives and audible those voices that might be neglected in traditional research studies" (p. 168). Both Lay (2002) and MacNealy (1999) focus on women in their discussions of feminist research, considered a traditional focus. I would like to expand this focus to include all marginalized people as, for example, does Sherwin (1998). Lastly, with respect to participatory design, I would like to note that the field of usability is also applicable. Salvo (2001) discusses usability as participatory design and notes "The technical communicator has an important role to play in moving the design and usability processes together…in blurring the distinction between the design and testing phases of product design" (p. 289). Soliciting and using input from the community who might interact with specific materials is practically useful as well as empowering.

St. Germaine-Madison (2008) examined the raw data from a report on Hispanic preferences for medical information compiled by Ogilvy Public Relations Worldwide (2005) and the Center for Disease Control and Prevention. Her examination resulted in a set of guidelines for technical communicators consider for Spanish speakers in the United States:

- Present information with an authoritative tone and a more technical vocabulary, but take special care to explain this information clearly for the audience

[12] Spinuzzi (2005) also discusses participatory research in his article, "The methodology of participatory design." His focus is action research, which is slightly different than what Johnson (2004) is describing.

- Strive for an associative style that connects themes according to topic rather than a linear style that focuses on time or order
- Clarify statements about risk so that the audience will understand what the risk means for them and their health or safety
- Consider the use of brighter, less muted colors because these are seen as more attractive by this population
- Use graphics that, whenever possible, depict Hispanics in a social setting, because these graphics are preferred over graphics that show individuals of different races or lone individuals (p. 245)

Notice that risk is specifically mentioned in these guidelines. Risk communication is another area within the field of technical communication that may be useful since the informed consent conference works to inform participants of the risks and benefits of the trial. A particularly applicable case study by Evia and Patriarca (2012) describes the process of developing safety and risk communications for Latino construction workers using direct input from those workers. Evia and Patriarca draw on the work of Sauer, who has written much on technical risk communication. Sauer's description of the cycle of technical documentation in large regulatory industries provides helpful notions (Sauer, 2003). This framework shows how individual documents "are the product of many individual moments of rhetorical negotiation" (p. 72). These moments of negotiation provide opportunities for transformation.

Evia and Patriarca (2012) noted that the existing safety documents they looked at were translations, often inaccurate, of materials authored in English. There existed "few culturally usable instructional materials …available to help them" (p. 341). The areas of translation and localization are applicable to this project but while localization will be discussed, translation, with its own large body of literature, will not be directly addressed. St. Germaine-McDaniel (2010) concludes, after a literature review of government

documentation for Executive Order 13166[13], that technical communicators are in the forefront in shaping the localization of health information. To accomplish successful localization, the technical communicator should consider the cultural group's "traditional views on medical information, wellness, and illness before they attempt to localize a document in terms of textual style, graphics, and color" (St. Germaine-McDaniel, 2010, p. 251). The next section, Intercultural Communication—Latino Culture, will address the incorporation of culture more thoroughly.

Bridges and borders are effective metaphors to use when discussing the inclusion of race and ethnicity in the practice, research, and pedagogy of technical communication. Race and ethnicity are intertwined with other concepts such as equity, language, ethics, nationality, access, and culture. Gómez-Peña (1993) points out that the society in the U.S. is unquestionably multiracial and multilingual. When cultures meet, he explains, there is a "border experience." The border, a politically prominent topic in the U.S. today, is a useful metaphor when contemplating the intersection of two or more cultures; the dominant culture in the U.S., Gómez-Peña argues, is border culture (p. 46). Therefore, I argue, technical communicators must acknowledge the myriad cultures that may be represented in our audiences and work to move along the continuum away from cultural hegemony toward a critical multiculturalism.

Kirk St. Amant (2011) observes that while technical communication has traditionally been practiced in Western nations, it now must function in a globalized workplace. To do so, technical communication educators must "equip students to succeed in today's globalized workplace" (p.3). To that end, Thatcher and St. Amant (2011) have edited a book that addresses various aspects of intercultural teaching and training. Scott (2010) provides a literature review on the topic of intercultural rhetoric in the technical communication curriculum. Scott (2010) concludes by listing the needs for future scholarship in intercultural communication and saying, "The need for a greater

[13] Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency," can be found at: http://www.justice.gov/crt/about/cor/Pubs/eolep.php.

emphasis on intercultural communication in technical communication curricula is becoming increasingly urgent" (p. 86). The next section looks at intercultural communication with a focus on Latino culture.

Intercultural Communication—Latino Culture

Intercultural communication, or cross-cultural communication, is studied in a number of fields including anthropology, psychology, technical and business communication, and applied linguistics, among others. Some scholars ascribe specific definitions to the terms *intercultural communication* and *cross-cultural communication*. Because of the varied literature, this project will essentially treat the two terms as synonymous. It is a big topic with a number of approaches. This review contains an overview of foundational theories and touches on literature from intercultural training and intercultural communication in the Latino culture.

Intercultural communication refers to communication across cultures—communication between individuals who negotiate meaning when they do not share the same perspectives. These perspectives are informed from their culture. Kreuter and McClure (2004) describe culture as "learned, shared, transmitted inter-generationally, and reflected in a group's values, beliefs, norms, practices, patterns of communication, familial roles, and other social regularities" (p. 440).

Anthropologist Edward T. Hall discussed the meaning of culture in his foundational book *Beyond Culture* (1976). Hall states,

> [Culture]…is shared and in effect defines the boundaries of different groups. Culture is man's medium; there is not one aspect of human life that is not touched and altered by culture. This means personality, how people express themselves…, the way they think, how they move, how problems are solved…(Hall, 1976, p.14).

This definition describes the integral role culture plays in defining social groups. Culture determines our perceptions, which affect the manner in which people communicate. Hall (1976) introduced the construct of high-context and low-context culture. At its most basic definition, a high-context culture is one whose communication style is indirect and situational. Meaning includes information derived from the physical context or from internalized information. Mexico and Latin America are considered moderately high-context cultures. A low-context culture is one whose communication style is direct and specific. Context is provided verbally. The U.S. is a low-context culture. For Hall (1998), culture is "a system for creating, sending, storing, and processing information" (p. 53). An understanding of culture is the basis of intercultural communication.

Related to Hall's theory is Triandis'(2004) research on individualism and collectivism. People in individualist cultures define themselves as unique individuals independent from the larger group while those in collectivist cultures define themselves as part of the larger group. With respect to communication, those in individualist cultures attend to the content of communications while in collectivist cultures, individuals pay attention to the context of the communications "how something was said, the gestures, the settings in which the communication occurred" (Triandis, 2004, p. x). Triandis names people from North America of European background, North and Western Europe, Australia, and New Zealand as living in individualist cultures; while people from Latin America, Southern Europe, East and South Asia, and Africa as living in collectivist cultures.

One criticism of Hall's construct, Triandis' research, as well as Hofstede's theory (described in the next paragraph) is that these theories tend toward generalizations, which could then lead to stereotyping. Kreuter and McClure (2004) describe culture as "learned, shared, transmitted intergenerationally,and reflected in a group's values, beliefs, norms, practices, patterns of communication, familial roles, and other social regularities" (p. 440). Cultures are not static, they are dynamic. In an effort to address this criticism,

inter-culturists Gudykunst & Kim (2003) describe two levels of cultural analysis, cultural and individual, stressing that while general cultural tendencies exist, individuals will share these tendencies to varying degrees. Keeping these levels in mind helps prevent a tendency toward stereotypes. Related to the cultural and individual levels of analysis, Bennett (1998) differentiates between cultural-specific and cultural-general approachesdescribing Hall's concept of low- and high-communication as a cultural-general approach and a central consideration to the study of intercultural communication. Gudykunst and Kim (2003) summarize this approach: "High-context communication can be characterized as being indirect, ambiguous, understated, with speakers being reserved and sensitive to listeners. Low-context communication, in contrast, can be characterized as being direct, explicit, open, and precise and being consistent with one's feelings" (p. 72). In addition to these aspects of speech, nonverbal behaviors hold much significance: "voice, gestures, eye contact, spacing, and touching all provide direct analogic expression of emotions that modify (in low context) or supplant (in high context) the verbal message" (Bennett, 1998, p. 17).

Another important theory in the field of intercultural communication was developed by Geert Hofstede. In his book, *Culture's Consequences*, (1980), Hofstede describes his study of 117,000 IBM employees in 66 countries. Through extensive analysis of this substantial data, Hofstede defined four value dimensions to describe culture—Power Distance, Individualism, Masculinity, and Uncertainty Avoidance. Hofstede treats the concept of culture "as the collective programming of the mind which distinguishes the members of one human group from another" (Hofstede, 1980, p. 21).

Looking at Mexico and Latin America in terms of these value dimensions is informative. With respect to individualism, Hofstede has labeled Mexico and Latin American countries as collectivist. (Hofstede, 1994). As a collectivist society, Mexican and Latin American cultures value group achievements over individual achievements. Relationships, especially familial relationships (*familismo*), hold priority and are given a high value. Considering the dimension of power distance, Mexico and Latin America

rank quite high. A high power distance is often seen in societies with an inequitable distribution of power and wealth. In such societies, power distances are autocratic and class divisions are accepted. Hofstede defines the dimension of masculinity in terms of behaviors rather than gender. Masculine refers to assertive behaviors and feminine refers to modest, caring behaviors. Specific to the Latino community is the concept of *machismo* or manliness. Defined in various ways, it is a constellation of values, ideals, and behaviors appropriate to the realization of manhood. An important element of *machismo* is the maintenance of the male's dignity and respect, or honor (Albert, 1996). Castillo, Perez, Castillo, and Ghosheh (2010) describe a related concept of *marianismo*, a term they report was coined by Evelyn Stevens. This term is used to describe idealized female gender roles. An idealized Latina is virtuous, humble, spiritually superior to men, submissive to the demands of men, and willing to withstand sacrifices and suffering for the family.

In addition to these cultural dimensions, the work by Triandis, Lisansky, Marín, and Betancourt (1984) on the cultural script of Latinos is important to consider. A cultural script is defined as "a pattern of social interaction that is characteristic of a particular cultural group" (p. 1363). Triandis et al. (1984) point to a concept they name *simpatía* as the cultural script among Hispanics. *Simpatía* is a Spanish term with no exact English translation, but refers to aspects of one's personality that allow others to perceive an individual "as likable, attractive, fun to be with, and easygoing" (p. 1363). An individual who is *simpatico* displays empathy and "behaves with dignity and respect toward others, and seems to strive for harmony in interpersonal relations" (Triandis et al. 1984, p. 1363). The avoidance of negative behaviors is rooted in the cultural values of *respeto* (respect) and *dignidad* (worthiness). Empirical research done be Triandis et al. (1984) confirmed the existence of this script. They also observed the existence and the influence of a high power distance (a power distance script) as revealed by the data of their study. Deviations from the *simpatía* script seem to be tolerated to some extent if they are come from a person with a high status. The next subsection describes how these concepts can be applied in health communication.

Culturally competent health communication. Specific to this project is the literature on culturally competent health communication. Elder, Ayala, Parra-Medina, and Talavera (2009) provide an overview of the research issues and challenges encountered when communicating health information to the Latino community. Aspects to be aware of are a "focus on family, cultural traditions, and collectivism while attending to acculturation, language, generation, and national origin (p. 207). Elder et al. (2009) appropriately note that the Latino Cultural is dynamic and includes complex societal transitions and adjustments. Health communication literature suggest McGuire's communication/persuasion model as a useful framework for examining how culture affects the adequacy of health communication (as cited in Kreuter & McClure, 2004).

Flores (2000), like Triandis et al. (1984), also points to the importance of understanding normative cultural values of the Latino culture. Specifically, Flores names *simpatía*, *personalismo*, *respeto*, *familismo*, and *fatalismo* (2000). He explores problems associated with limited English language proficiency and the culturally constructed diagnostic categories readers might know by the term "folk illnesses" (p. 18). Andrés-Hyman, Ortiz, Añez, Paris, and Davidson (2006) present normative values that they refer to as cultural concepts. Their identified concepts include *dignidad y respeto*, *familismo*, *personalismo*, *machismo*, *marianismo*, religion and spirituality. The authors elaborate on the cognitive and behavioral implications related to these concepts. An acknowledgement and understanding of these elements are essential to building cultural competency. The adequacy of cultural competency directly affects health outcomes such as adherence.

There has been a sizable amount of research on the role of Latino culture in healthcare generally. Examples include interpersonal and print nutrition communication research (Elder, Ayala, Parra-Medina, & Talavera, 2005), adaptation of the preventive intervention program for depression (D'Angelo et al., 2009), health storytelling in Latino media (Wilkin & Ball-Rokeach, 2006), and the identification and comparison of the

coping strategies of Latina and European-American mothers of children with cancer (Johns et al., 2009).

Little research has been done to study the informed consent conference in a multicultural setting and almost none concentrating on Latinos. One multicultural study, Simon and Kodish (2005), concluded that "Further research is needed to understand how cultural factors affect outcomes such as parental understanding, decision making, mutual trust, and satisfaction within the informed consent process" (p. S124). Candilis and Lidz (2010) call for more research on the aspect of trust because it is not well studied, "[the]importance of trust in the informed consent process, [is] a factor potentially both more powerful and less well examined than aspects of disclosure and comprehension studied in so much of the empirical research on informed consent" (p. S8).

The next chapter describes Study 1 of this research project, with sections on Method, Results, and Discussion.

Inter-text

Being recruited into trial is like being recruited into the Navy,
issues of misrepresentation and racism

Yeah it's like recruiting people. I remember very early in my 30s I almost get recruited by the U.S. Navy and they were chasing me, calling me and all this trials remind me of that 'cause they call you and so they are calling me all these guys, this officer and he wanted to talk to me, so finally I got to the officer and I talked to him and I say well let me think about it. He wanted me to sign the papers but then he painted me these beautiful world of traveling around the world you know, in Japan, in the Bahamas, and all those places and all this and all these new faces and friends that I was going to meet in Europe and Spain in all these places and you know it sound good and this money that was going to come to me and if I desire to go and achieve higher education they will help me, you know, fund that, so it sounded all so good but eh, it sounded too good to be true. So what I did, I visited ahh two retired U.S. Navy people, older men, and first thing they told me right away said don't go in there. Yeah, one, both of them, were retired as officers their whole life, yes, and they gave me different reasons said do you have a profession? And I said why? It's just that, uhh, it's not how they paint it, it's different. There's a lot of racism. Latinos don't have a chance to ever become um ahh admiral or any higher officer position, don't have a chance, it's always given to people of white descendants.

Ahh you have to work twice as hard as the others, people of color have to work twice all the time in those places. You're not going to get to see the world because you're always in close ship with those big walls and you don't see nothing, so it's, you're just out there knowing not where you're going so all those things that they tell you is just a way to grab you and no, I never signed it and I went back; yeah, yeah they didn't want to depress me more after that (laughs) It was fine, I said no it's not worth it and I made the right decision. I'm happy about it.

Chapter 3: Study 1

Methods

Bueno aconsejar, major remdiar

It is good to give advice, but it is better to solve the problem

Introduction. This qualitative research project utilizes a version of the inductive research methodology known as grounded theory. This is a rigorous methodology that employs the following processes: data collection, coding (initial, focused, and theoretical), memo writing, theoretical sampling, saturating theoretical categories, and finally, theorizing. The result is a unique theory specific to and grounded in the data.

I am providing a history of grounded theory to assist those who may be unfamiliar with the methodology. This history is also intended to illustrate my philosophical understanding of the approach, and to demonstrate why this methodology is appropriate to examine the questions grounding this study. Considering the previous use of this methodology in informed consent research and considering that this methodology allows unforeseen areas of inquiry to surface, it is an appropriate research methodology for the relatively unexplored topic of enrolling Latino immigrants with little to no English language skills into clinical trials. Grounded theory provides a means to capture insight into the efficacy of the informed consent conference for trial enrollment as well as allowing this particular population a voice in the informed consent process.

The overarching question I am looking to answer is this: How do Latino immigrants with little to no English language proficiency negotiate a clinical trial informed consent process? Specifically, the research questions that will inform this inquiry are:

R1: What do Latino immigrants understand from the informed consent process?

R2: Is there information important to the participants that is not being communicated?

R3: How adequate is the structure of the informed consent conference?

To fully understand how this project progressed I provide a detailed description of how I located and recruited the participants for this phase of data gathering, a detailed description of the research design and methods, and finally a thorough description of the data analysis.

Methodology: Grounded theory.

History of grounded theory. To understand grounded theory one must first look at the historical context into which it was created and introduced. In the mid-1960s, qualitative research was losing favor to positivist methods in quantitative research. The focus on the scientific method resulted in a narrowing of research opportunities for social scientists since "[t]he priority they [quantitative researchers] gave to replication and verification resulted in ignoring human problems and research questions that did not fit positivistic research designs" (Charmaz, 2006, p. 5). Qualitative research could not, it was believed, be adequately verified.

In 1967 Barney G. Glaser (1930–) and Anselm L. Strauss (1916–1996) published their seminal work, *The Discovery of Grounded Theory*. Glaser had been trained at Columbia University and worked under the direction of Paul Lazarsfeld (an innovator of quantitative methods) and Robert Merton (known for his middle-range theories[14]). The Columbia tradition stressed associating empirical research with the development of theory. Strauss was trained at the University of Chicago ('Chicago School' of sociology) and was influenced by interactionist and pragmatist writings

[14] Merton (1957) explains middle range theories as those "…about a delimited range of social phenomena" (p. 109) and the abstractions of these theories are closely associated with the data of the observations. Middle range theories are contrasted with Parson's work as cited in Merton, 1957) toward a comprehensive sociological theory.

including those by Herbert Blumer (symbolic interactionism[15]) and George Herbert Mead's social psychology and ethnographic field research (as cited in Strauss & Corbin, 1990; Bryant & Charmaz, 2007). Their paths crossed at the University of California, San Francisco. Glaser and Strauss (1967) note in the preface of *The Discovery of Grounded Theory* that neither academic tradition, Columbia's positivistic quantitative methodologies, nor the 'Chicago tradition' of pragmatism, had "been successful at closing the embarrassing gap between theory and empirical research" (p. vii). Social and behavioral sociologists had been successful in improving methods for testing extant theory, Glaser and Strauss observe, but not in generating theory. *The Discovery of Grounded Theory* describes the systematic methodological strategies used in the research they conducted that resulted in their co-authored book *Awareness of Dying* (1965). Glaser and Strauss explain, "[o]ur basic position is that generating grounded theory is a way of arriving at theory suited to its supposed uses. We shall contrast this position with theory generated by logical deduction from *a priori* assumptions" (Glaser & Strauss, 1967, p. 3). They had provided sociologists and other scholars a plausible method to discover "abstract theoretical explanations of social processes" (Charmaz, 2006, p. 5). This method was systematic and methodical, containing an aspect of verification, thus mirroring aspects of positivistic quantitative research.

Bryant and Charmaz (2007) assert the key strength of grounded theory is that it "builds on methodological concepts of empirical grounding derived from the quantitative orientation" (p. 33) and applies analytical steps familiar to Chicago School field researchers of the time. The key weakness of grounded theory is "the positivist, objectivist direction they gave grounded theory" (p. 33). The title of Glaser's and Strauss' book, *The Discovery of Grounded Theory*, reflects an epistemological orientation that claims reality can indeed be discovered and understood. Bryant and Charmaz (2007)

[15] Symbolic interactionism is a termed coined by Herbert Blumer (1969) and is based on three premises: "[first that] human beings act toward things on the basis of the meanings that the things have for them…[second] is that the meaning of such things is derived from…the social interaction that one has with one's fellows…[and third] these meanings are handled in, and modified through, an interpretative process used by the person in dealing with the things he encounters" (p. 2).

caution that one cannot expect to achieve a full understanding of the methodology of grounded theory just by reading *The Discovery of Grounded Theory*. Rather, they advise reading what they understand to be four founding texts by Glaser and Strauss: *Awareness of Dying* (1965), *The Discovery of Grounded Theory* (1967), *Time for Dying* (1968), and *Status Passage* (1971).

Philosophical ground was laid for the acceptance of grounded theory in part through Thomas Kuhn's unique critique of positivism and the work of 'normal science'. Kuhn, in *Structure of Scientific Revolutions* (1962), puts forth the notion that science acquires new knowledge by experiencing revolutions called 'paradigm shifts'. Normal science, defined as "research firmly based on one or more past scientific achievements that some particular scientific community acknowledges for a time as supplying the foundation for future practice" (p. 10), progresses until enough evidence contrary to the current paradigm(s) accumulates. A crisis then occurs and continues until the community negotiates a new paradigm. The implications of this theory of science are that fixed science does not exist; new knowledge is negotiated. This held great interest for those interested in epistemology and qualitative research.

After *The Discovery of Grounded Theory*, Glaser and Strauss published on grounded theory separately, Glaser in 1978 with *Theoretical Sensitivity: Advances in the Methodology of Grounded Theory* and Strauss in 1987 with *Qualitative Analysis for Social Scientis*t (the texts listed in the previous paragraph, *Time for Dying* and *Status Passage* are monographs on research done by Glaser and Strauss, not books about grounded theory). It should be noted that I have not and will not be listing all texts published by Glaser and Strauss throughout their careers. At this point in time, Strauss, in collaboration with Juliet Corbin, took the grounded theory methodology in a different direction in their coauthored works, *Basics of Qualitative Research* (1990) now in its fourth edition, and *Grounded Theory in Practic*e (1997). Annells (1997) offers a detailed account of the differences between Glaser's version of grounded theory, which is the original version put forward in *The Discovery of Grounded Theory*, often referred to as

classic grounded theory, and the version of Strauss and Corbin (1990). Annells (1997) grounds this history within the five moments of qualitative research.

In the classic grounded theory, the researcher's focus is on a general area of interest, while Strauss and Corbin focus on a pre-identified problem. The goal in classic theory is to *generate* an inductive grounded theory where Strauss and Corbin are looking to *develop* a grounded theory. Annells (1997) describes the development this way, "[t]he researcher and the researched cocreate, or *develop*, the research product, rather than it *emerging* from the data. It is constructed rather than found" (p. 124). Additionally, instead of stressing the comparative methods of classic grounded theory, Strauss and Corbin focus on the techniques they put forward. These techniques include axial coding and the causal-conditional matrix. Axial coding is "a way of specifying the dimensions of a category, relating categories to subcategories, delineating relationships between them" (Charmaz, 2006, pp. 159–160). The causal-conditional matrix is a coding device to look at the structural contexts linking structures and situations. The Strauss and Corbin method continued to evolve and recognize the influence of macro-social factors, becoming less prescriptive. In an interview with Cisneros-Puebla (2004) Corbin described the philosophy that she and Strauss used to inform their approach to grounded theory this way: "We come from an interactionist, Deweyian, and philosophical tradition, with a little constructionism and post-modernism thrown in" ("To Learn to Think Conceptually," par. 21).

Classic grounded theory calls for a suspension of the researcher's preconceptions. The tension between Glaser and Strauss is centered on the approach to analysis. Glaser firmly believed grounded theory should be absolutely inductive:

> The first step in grounded theory is to enter the substantive field for research without knowing the problem. This requires suspending your knowledge, especially of the literature, and your experience. The

> researcher must take a 'no preconceived interest' approach and not ask questions that might be on his mind (Glaser, 1998, p. 122).

Alternatively, Strauss and Corbin value previous experience. They observe, "Each of us brings to the analysis of data our biases, assumptions, patterns of thinking, and knowledge gained from experience and reading" (1990, p.95).

The classic grounded theory's dictum of delaying a literature review until the discovery of the theory has been subject to criticism. Thornberg (2012) offers his arguments for using extant literature which he terms *informed grounded theory*. Thornberg defines his *informed grounded theory* concept this way:

> What I call *informed grounded theory* refers to a product of a research process as well as to the research process itself, in which both the process and the product have been thoroughly grounded in data by GT [grounded theory] methods while being informed by existing research literature and theoretical frameworks (2012, p. 249).

Among the problems with delaying the literature review, Thornberg lists the following:

- If a researcher is prevented from reading literature in the area of research, it would be impossible to research in one's own area of expertise.
- Researchers will soon find a reduction of possible research fields of which they have not read the literature.
- Researchers are often required to present a literature review to obtain institutional review board (IRB) approval to do their research or to obtain funding.
- There is a possibility that the unique theory the researcher discovers may already exist.

Glaser's position on familiarity with the literature is a bit confusing as Thornberg (2012) notes. While urging researchers to avoid "contamination" by reading relevant literature, Glaser urges researchers to enhance their theoretical sensitivity by having knowledge and reading literature in areas unrelated to the research project. In contrast, Strauss and Corbin (1990) say, "Each type of literature tends to be useful in somewhat different and specific ways, yielding diverse sorts of ranges of data…or research findings, or theoretical formulations" (p. 56).

Scholars subsequently began to move grounded theory away from its positivistic underpinnings. Charmaz (1990, 2000, 2002, 2005, 2006, 2009) provides yet another version of grounded theory. Chamaz was taught classic grounded theory by Glaser in graduate seminars at the University of California, San Francisco, and Strauss was her dissertation chair. Her version acknowledges classic grounded theory as well as "tak[ing] into account the theoretical and methodological developments of the past four decades" (Charmaz, 2006, p. 9). Chamaz (2006) incorporates a symbolic interactionist theoretical perspective, which directs us to "*construct* our grounded theories through our past and present involvements and interactions with people, perspectives, and research practices" (p. 10). The data are co-constructed by the researcher and the participants; it is not simply observed phenomena.

According to Charmaz (2006), "The constructivist position views research as an emergent product of particular times, social conditions, and interactional situations" (p. 160). Constructivists feel the research method resides within the research process. The research method is not comprised of prescriptive methodological rules, but rather principles and practices that are to be used as guidelines. Charmaz (2006) comments, "Researchers who treat grounded theory as consisting of a few flexible yet systematic guidelines create the conditions to define emergent categories" (p. 161). Diverging from the classic grounded theory of Glaser and Strauss that claimed the researcher would discover the theory emerging from the data, Charmaz, following a symbolic interactionist theoretical perspective, believes that what comes from the data is an interpretive

portrayal, not an exact replica. To view a flowchart detailing the grounded theory process as conceived by Charmaz, see Appendix C.

Grounded theory in general, not just the classic version, has been and is subject to critique. Thomas and James (2006) are vigorous in their criticisms. They explain the purpose of their article "is to challenge the continuing legitimacy of grounded theory and the lofty place its methods have come to hold in social and institutional analysis" (p. 768). After providing an accounting of other scholar's objections and critiques, Thomas and James (2006) take issue with three key terms: *theory*, *ground*, and *discover*. I will take up just one of these complaints, the use of the word *discover*. The authors argue that grounded theory makes a rather vast claim in promising a method of discovery. They point out that discovery implies the "disclosure of well-hidden but already-existing phenomena" (p. 786). The researcher is discovering static things that already exist. They prefer *invention* because the word *invention* "implies a unique construction among a plethora of possible constructions" (Thomas & James, 2006, p. 786). This is not far from the claims Charmaz makes when discussing her version of grounded theory. She says, "we are part of the world we study and the data we collect. We *construct* our grounded theories through our past and present involvements and interactions with people, perspectives, and research practices" (Charmaz, 2006, p. 10). Charmaz (2006) also says, "My approach explicitly assumes that any theoretical rendering offers an *interpretive* portrayal of the studied world, not an exact picture of it" (p. 10). One researcher's interpretive portrayal, we can assume, may differ from another researcher's interpretive portrayal. Charmaz, using the word *construct* rather than *invention* leaves open the possibility of multiple interpretations. I have adopted the constructivist grounded theory methodology developed by Charmaz for this project. As such, it is important to understand and acknowledge my involvement as the researcher. Mauthner and Doucet (2003) remind us "that as researchers we need to be reflexive about, and articulate, the ontological nature of subjects and subjectivities we are using in our research as well as the epistemological assumptions underpinning our methods of data analysis and

knowledge construction" (p. 416). To view my depiction of my role as the researcher in this project, see Appendix D Positioning Myself in the Research.

Use of grounded theory in medical and bioethics research. The first utilization of grounded theory was the field studies done by Glaser and Strauss looking at chronic illness and dying. Strauss was in fact, known as a medical sociologist. After the introduction of this methodology in *The Discovery of Grounded Theor*y (1967), many fields adopted the method, including sociology, education, social work, nursing, and bioethics (Strauss & Corbin, 1994). Some fairly early studies include the management of a hazardous pregnancy (Corbin, 1992), ovarian egg donation between sisters (Lessor, 1993), and experiences with chronic illness (Charmaz, 1990).

Grounded theory methodology began to be used in bioethics research in the 1990s, when social science became more accepted in the field[16]. Studies on informed consent and on participation in clinical research employing grounded theory methodology include an examination of communication that takes place during the informed consent conference for pediatric Phase I cancer trials (Marshall et al., 2012), an investigation of people's experiences of and attitudes about participation in clinical trials (Lococ and Smith, 2011), an examination of gender differences in beliefs and attitudes of African Americans about participation in clinical trials (BeLue, Taylor-Richardson, Lin, Rivera, and Grandison, 2006), and an examination of the consenting process in an operating room direct admissions department (Agnew and Jorgensen, 2012).

As discussed, the constructivist approach to grounded theory "places priority on the phenomena of study and sees both data and analysis as created from shared experiences and relationships with participants" (Charmaz, 2006, p. 130). This approach acknowledges my research goal of working *with* this community rather than *looking* at the community member's views. It also provides the possibility for cocreated knowledge

[16] See Chapter 2 Literature Review for more on the integration of social sciences into the discipline of bioethics.

to return to the community. Finally and importantly, this approach looks at where and how the studied phenomena "is embedded in larger and, often, hidden positions, networks, situations, and relationships" (Charmaz, 2006, p. 130).

The grounded theory methodology includes the following processes: data collection, coding (initial, focused, axial, and theoretical), memo writing, theoretical sampling, saturating theoretical categories, and finally, theorizing. For Study 1 of this project the data to be examined includes:

- Textual artifacts from the NET-Works Study
- Interview transcripts
- Observational notes (taken during interviews)
- Photos of interview sites
- Conversations with interpreter, persons associated with interview sites, José Rico (NET-Works enroller)

Initial research questions. Grounded theory is meant to answer the question: What's happening here? Charmaz (2006) offers a list of questions to help the researcher reflect on what they are seeing and hearing. I am including them here to help the reader understand what elements a grounded theorist might be looking for:

- From whose point of view is a given process fundamental? From whose view is it marginal?
- How do the observed social processes emerge? How do participants' actions construct them?
- Who exerts control over these processes? Under what conditions?
- What meanings do different participants attribute to the process? How do they talk about it? What do they emphasize? What do they leave out?
- How and when do their meanings and actions concerning the process change? (p. 20)

Understanding that the research questions may evolve or be replaced, I began this research with the following overarching question: How do Latino immigrants with little to no English language proficiency negotiate a clinical trial informed consent process? Specifically, the research questions that inform this question are:

R1: What do Latino immigrants understand from the informed consent process?

R2: Is there information important to the participants that is not being communicated?

R3: How adequate is the structure of the informed consent conference?

Participants.

Historical context. The Study 1 data was gathered in the fall of 2013. Nationally, President Obama had deported more than 1.9 million foreigners since taking office in 2009, a record number for any one president. 98% of those deported were "criminals, serious immigration offenders, and recent border crossers" (Preston, 2013, para. 5). During fiscal year 2013, 368,000 people were deported. (Preston, 2014, para. 7).

Locally, the city office of U.S. Immigration and Customs Enforcement had conducted a raid at three locations of a Spanish immersion day care chain during the summer months, causing the departure of approximately 60 teachers and workers—40% of the entire staff (Brunswick, 2013). The school spokesman told a reporter that "employees have passed a series of background checks—including the federal verification and a state Department of Human Services (DHS) background check required for all day-care workers—and a separate check of references, education certificates and past employment conducted by the day care's owners" (Brunswick, 2013, abstract). However, the state criminal background check does not examine immigration status.

Location. The recruitment location for Study 1 of this project was a Catholic church that serves a large Latino population and is located in an urban community. The parish priest and the parish administrator agreed to allow this research to take place in the parish. Women and men, who are parents, were recruited to participate. I chose this location for several reasons: 1) it provided access to a convenience sample of participants; 2) it provided the participants, the majority undocumented immigrants, a place that felt safe and familiar; 3) it provided a location that was assessible to the participants using available transportation; 4) previous research I had conducted with this same population, "Effective Intercultural Healthcare Materials" (Pigozzi, unpublished manuscript), confirmed that the participants felt comfortable holding conversations in the churches and that providing food (meals or snacks) and activities or a caregiver for accompanying children was culturally appropriate and appreciated.

To protect confidentiality the parish does not keep a record of the parishioner's names and their contact information. With respect to my research, the name and location of the research site will not be referenced by name in any document I author other than the Institutional Review Board (IRB) application(s).

In qualitative research and, more specifically, grounded theory research, the goal is saturation of categories[17] and how quickly saturation is reached is dependent on the researchers questions and goals. Speaking about their experience in research, Guest, Bunce, and Johnson (2006) observe that "if the goal is to describe a shared perception, belief, or behavior among a relatively homogeneous group, then a sample of twelve will likely be sufficient" (p. 76). Charmaz (2006) says 25 participants may be sufficient for small projects. Green and Thorogood (2009) explain, "the experience of most qualitative researchers is that in interview studies little 'new' comes out of transcripts after you have interviewed 20 or so people" (p. 120).

[17] Categories are considered 'saturated' "when gathering fresh data no longer sparks new theoretical insights, nor reveals new properties of these core theoretical categories" (Charmaz, 2006, p. 113).

I classify this project as relatively "small." I also describe the participants as homogenous along certain dimensions. Those dimensions include a belief and value system based on their shared religious beliefs, sharing the immigrant experience, sharing the experience of being an undocumented immigrant, for the most part sharing a country of origin, sharing a first language of Spanish, and the participants currently live in a similar geographic location.[18] With these considerations in mind, I chose to apply to speak with 20 participants in the initial IRB application.[19]

Recruitment. I first obtained permission to recruit participants by sending an email to the parish priest in which I introduced myself and my research plan. I was directed to communicate with the parish administrator. The first email was sent in July 2013 with the introduction of the research to the community taking place on September 8, 2013, followed by a series of interviews and focus groups held on September 13, 2013, September 15, 2013, September 27, 2013, and September 28, 2013.

Communications with the parish administrator included a face-to-face meeting to explain the project and give him an opportunity to ask questions. Email discussion topics during this period dealt with many logistical issues including the recruitment flyer, the introduction of the project to the community, available dates, and the location of the research interviews.

At the suggestion of the parish administrator, I and the interpreter introduced the study and invited parishioners to participate during the announcement period of two well-attended Sunday masses on September 8, 2013. A table was set up in the church foyer where participants could sign up for an interview time. Additionally, recruitment flyers (Appendix E) were posted around the church property. I and the interpreter took names and phone numbers (which were destroyed after the phone calls) in order to call the participants to remind them of their interview date and time.

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[18] Please refer to Chapter 1: Introduction, subsection Terminology, for an explanation of how I am viewing the population I am calling Latino.

[19] This research was conducted under IRB #1210P22682.

Research design and methods. In order to explore how Latino immigrants with little to no English language proficiency negotiate a clinical trial informed consent process I needed a way to either observe this population being recruited into a clinical trial or simulate the process. Patient populations are difficult to locate for consent research. I spent 13 months, intermittently, attempting to gain access to enrollments in existing clinical trials with no success. The requirement that the potential trial participants be Latino with limited English language skills made locating a trial even more complicated. Candilis and Lidz (2010) acknowledge the difficulty of joining existing clinical trials to conduct consent research. This "piggy-backing" is difficult for a number of reasons. The trial researchers may be concerned that their patients will be reluctant to join their trial with the additional consent research; they may be concerned that their trial is being judged, or they may be concerned about the additional burden to their patients and staff.

It is for these reasons that I adopted the use of analogue patients, who hereafter will be referred to as analogue participants. Analogue participants are research participants who are asked to imagine that they are the patient, or in this case a potential clinical trial participant, in a particular medical circumstance that is depicted in a video. "This methodology has been used in previous studies in an attempt to understand patient perceptions when an actual patient population is not available" (Blanch-Hartigan, Hall, Roter, & Frankel, 2010, p. 316).

A major criticism of the use of analogue participants involves the fact that it is virtually impossible for an individual to imagine they are suffering from a chronic or serious illness; therefore their response may not be representative of the response of an actual patient. To counter this objection I chose to simulate enrollment into a healthy patient trial, as it is a situation that is reasonable for an analogue participant to imagine. The trial chosen was an actual trial, "NET-Works: Now Everybody Together for Amazing and Healthy Kids," underway in a university in the upper Midwest of the U.S. Permission to use the consent script and accompanying textual artifacts was given by the

Project Director, Division of Epidemiology & Community Health. Additionally, a Spanish-speaking enroller for the actual trial helped to create two videos. The first video is a priming video, which features the enroller, looking straight into the camera, explaining why the participants are being asked to enroll in this trial. The enroller provides the background necessary for the analogue participant to understand what the simulation entails. In the second video the enroller, again looking directly into the camera, conducts the clinical trial recruitment conference. Both videos use the scripts from the study "NET-Works: Now Everybody together for Amazing and Healthy Kids" and are recorded in Spanish, Appendix J and Appendix K. The use of videos provides a consistent stimulus for this trial. Additional information on the NET-Works trial can be found in Chapter 3 Results.

All materials and conversations in this trial were in Spanish to ensure a comfort level for the analogue participants and, more importantly, to remove language as a variable. Though I am proficient in Spanish, I am not a native speaker and am not completely fluent, especially in colloquial Spanish. An interpreter was present at all interviews to ensure that no meaning was lost and that the conversation flowed logically and freely (see Appendix F for biographies of the primary interpreter and the second translator who participated in the project). All sessions took place in the dining room of the parish rectory with refreshments provided (see Figure 1. Study 1 research site).

Figure 1. Study 1 research site

At the start of each session, I thanked the participants for coming and offered them a snack. Toys were available for accompanying children. I then explained the intent of the study, and the analogue participants were given this study's informed consent form (Appendix G). If requested or if we sensed it necessary, I or the interpreter read the consent form aloud in Spanish to aid those with low literacy. At this time any questions or concerns were addressed, and the analogue participants were asked if they would like to continue with the trial. Though mention of audio taping the interviews had been made in the consent form, I reiterated that procedure and asked if the analogue participant was comfortable with the taping. I explained that I wanted to hear everything they had to say and it would be difficult for me to remember our conversation without the tape. Signatures were not required on the consent form (through IRB permission), although I offered each participant a copy to keep for their records.

I then administered a short demographic questionnaire (Appendix H) and a verified health literacy assessment tool, "The Short Assessment of Health Literacy for Spanish Adults" (SAHLSA-50) questionnaire. The SAHLSA-50 questionnaire assesses a Spanish-speaker's ability to read and comprehend medical terms (Lee, Bender, Ruiz, & Cho, 2006) (Appendix I). Health literacy refers to the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Both of these, the demographic questionnaire and the SAHLSA-50 instrument, were administered orally if requested or if I suspected it would make the participant more comfortable with the process. The SAHLSA-50 instrument was read to participants when it was used in a focus group, representing an adaptation of the original intent of the tool, which is to also assess reading ability and traditional literacy.

Prior to showing the videos (Appendix J Priming Video & Appendix K Conference Video), I briefly defined the concept of clinical trials and explained the concept of being an analogue participant specifically that they would be pretending to be in this situation. Then the analogue participants were given the NET-Works trial invitation letter to read or have it read to them (Appendix L). They were instructed to pretend that this letter had arrived in the mail at their home and a week or two after their receipt of the letter imagine that the enroller in the video has come to their home. To simulate this visit, the analogue participants were shown the priming video, which provides the background necessary for the analogue participant to understand why the analogue participant's physician has suggested they consider participating in this clinical trial. At this time, the analogue participants were given the NET-Works informed consent form and were asked to consult it while viewing the conference video (Appendix M).[20]

[20] The actual NET-works study used two laminated cards with visuals to help explain aspects of the study. I intentionally chose not to use these in order to make the conference more generic.

An audio-recorded interview with each analogue participant followed the viewing of the videos. Interviews are compatible with grounded theory because they are somewhat guided, yet allow for emergent data. A semi-structured interview format was initially chosen over a focus group format after considering the advantages and disadvantages of each method as well as the cultural values of the analogue participants (Marshall & Rossman,2011; Babbie, 2007). For example, the cultural value of *simpatía* (Triandis, Lisansky, Marín, & Betancourt, 1984) may play a role since Latinos typically do not like to create conflict or openly disagree with someone. Therefore, a strong opinion verbalized in a focus group may effectively extinguish other opinions. However, the reality was that though one person signed up for each interview slot, participants would often arrive with family members and neighbors. When this occurred, the interview was treated as a small focus group (Marshall & Rossman, 2011; Krueger & Casey, 2009). Original interview questions can be found in Appendix N. All interviews and focus groups were conducted in a semi-structured manner. At the end of each interview or focus group the participants were thanked and given a $15 Cub Food gift certificate. We stopped interviewing at 15 participants since we were in danger of exceeding our allotted limit of 20 participants due to the unexpected numbers of participants who could potentially join other interviewees. Therefore, an IRB "Change of Protocol" request was submitted to allow ongoing interviewing for Study 2 of data gathering.

Data analysis. The grounded theory methodology includes the following processes: data collection, coding (initial, focused, and theoretical), memo writing, theoretical sampling, saturating theoretical categories, and finally, theorizing. I employed advice from Saldaña (2013), *The Coding Manual for Qualitative Researchers;* Miles, Huberman, and Saldaña (2014); *Qualitative Data Analysis; A Methods Sourcebook;* as well as Charmaz (2006), *Constructing Grounded Theory* to analyze the data.

All audio recordings were transcribed and translated into English. Possible limitations and complications that might arise from translating from one language into

another will be addressed in the Chapter 7: Implications, Research Quality, Limitations, Future Research.

I began the analytical process with initial coding to break the data into parts using the analytical tool NVivo, a software program for managing quantitative data. NVivo specializes in non-numeric data such as field notes and interviews; it also manages PDF files and as such is a good way of incorporating pertinent literature. It facilitates coding across all inputted data and facilitates connections within the codes—something that reflects grounded theory methodology. I loaded the following materials into the NVivo program:

- Audio recordings of interviews
- Translated transcriptions of recordings
- Memos
- Photos of research site #1
- All textual materials from the public health trial
- All Pigozzi study materials

At this stage, all codes are "provisional, comparative, and grounded in the data" (Charmaz, 2006, p. 48). The goal of initial coding is to search for processes, "participant actions that have antecedents, causes, consequences, and a sense of temporality" (Saldaña, 2013, p. 103). The first pass resulted in descriptive nouns attached to topics. This is not useful to the grounded theory methodology's search to identify processes. To rectify this, I re-coded the data using gerunds when possible, as recommended by Charmaz (2006). I also employed in vivo coding. In vivo coding, or emic coding, is the use of the participant's words or phrases as the code. Saldaña (2013) notes that this method is useful in "studies that prioritize and honor the participant's voice" (p. 91). All initial codes were defined. This initial coding stage is used to bring to light gaps in the existing data and to suggest additional or substitute research questions. The unit of

analysis was an utterance that was then coded by complete thought, which may involve one or more sentences (see Table 1. Example of Initial Coding).

Table 1. Example of Initial Coding

Transcript (participant spoke in English—no translation needed)	Initial codes
Interviewee: My opinion would be to make a meeting of a group of people to specify personally to all of them together, to listen to them and send them all of the information ahead of time by postal mail so they can read it, so then can really understand.	Gathering possible participants into group Listen to them (in vivo) Sending information by mail before meeting
Because then if they go or they go without knowing what they're going to learn, they won't understand or they'll take kids with them and they won't pay attention.	Knowing topic in advance important Restricting understanding
But if they have something, a base or something upon to refer to, they'll go and they'll understand better.	Facilitating understanding
And it's a little repetitive. If you go to a house, you'll…well I think it's important that when you start your study, be direct. Because if you go and you explain it and they get bored. That's direct.	Communicating in a direct manner
And when you go, say quickly the main points. Like when you do a PowerPoint, the main points are highlighted. And that's what you do in your investigation.	Focusing on main points

I wrote memos that describe impressions and insights from each coded transcript. The memos also examine the similarities or differences between the transcripts. This

effort was to inform focused coding and direct future data collection. In each memo I fore-fronted Charmaz's (2006) reminders for writing early memos (see Table 2. Case-Based Memo Example).

Table 2. Case-Based Memo Example

Memo: 9-28 Participant #2 After initial coding
Charmaz (2006) memo tips (p. 80) Record what is happening in the data Use memos to direct and focus further data collection What is going on in the field setting or within the interview accounts? Can you turn it into a pithy category? Examples: 'avoiding disclosure,' living one day at a time,' surrendering to illness' What are people doing What is the person saying? What do research participants' actions and statement take for granted? How do structure and context serve to support, maintain, impede or change their actions and statements? What connections can you make? Which ones do you need to check? Look for processes **Context** In the dining room of the rectory. Refreshment on the table (juices, bottled water, apples, cookies). This man was very willing to talk and very candid. From previous observations he (and his family) seem very involved in the community and parish. The wife was sponsoring some sort of meeting on the immigration issue. They had a son who Elizabeth and I spoke to after mass one Sunday. The son wanted to study engineering at the U, had a very high ACT score. **Interesting:** Concerned that the study was too complicated, too layered Did not like, what he felt, was the emphasis on the participant's compensation. He

Memo: 9-28 Participant #2 After initial coding
thought the study should emphasize bettering the life of the family, especially the children Was clear that it was not possible to generalize over the Latino population because people have been in the U.S. differing amount of time and come from different countries Only participant to date that has brought up issue of having a primary care doctor and healthcare Quite concerned with who might see the study results – federal government? Insurance company? How is confidentiality guaranteed – overseen? Noting that technology contributes to sedentary and isolating behaviors (in youth) Only participant to date to mention hair sample – said "Caucasians" would not allow that – does that imply Latinos are being taken advantage of? Good observation – just because you are a mandated reported doesn't mean you are qualified to correctly identify abuse Hinted at possibilities of power issues in consent conference – importance of racial concordance Metaphor of being recruited into the Navy for informed consent conference – quite interesting – pointed to issues of misrepresentation, unethical practice, racism **Similarities to other interviews** Emphasis on bettering their lives, especially the children Takes time to participate – time in short supply due to need to work (perhaps several jobs) Latinos are finding their time with their family limited due to working Talked about how families are broken apart by (incorrect) mandated reporting Have a community member who has participated give testimonial **What's taken for granted:** Need to be cautious, may be being taken advantage of, may be underlying issues to protect yourself against

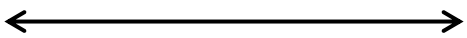
Next, I performed an initial round of focused coding to begin to identify the most important categories in the data corpus. According to Saldaña (2013), "Focused coding enables you to compare newly constructed codes during this cycle across other participant's data to assess comparability and transferability" (p. 217). I examined each initial code to clarify its meaning, to put it into context within the general conversation, to look at it against the emerging focus codes, and to look for applicability to one or more research questions. To physically visualize emerging categories, I wrote out each initial code that had been developed in NVivo on a Post-it brand sticky note (see Figure 2. Initial codes).

Figure 2. Initial codes

I was then able to physically rearrange and categorize the codes, writing focus code memos to systematically consider and record emerging categories, relationships and processes. With the emergence of each category, I physically placed all applicable initial codes under the new code and made notes of these lists. Grounded theory asks the

researcher to work toward a saturation point—a point where no new categories are being generated. This is accomplished with the constant comparative method. As the process continued, focus codes evolved into conceptual categories. I wrote memos in order to consider and record emerging conceptual categories and construct conceptual frameworks. An example of a very early conceptual memo is shown in Table 3. Conceptual Memo Example.

Table 3. Conceptual Memo Example

Memo: Conceptual Memo—exploring the continuum Process—Social processes or actions—what happens and how people interact (Sbaraini) What needs to be true of *A*, *B*, and ℓ if it is to be justifiably said that *A* consented (to *B*) to ℓ? Examining the gap between a morally valid consent and a legally adequate consent ¿Entiende? Look at what defines/describes the ends of this continuum: 	
Morally valid	Legally adequate
Competence (Beauchamp) This is a precondition, not part of the process	Competence (Beauchamp) This is a precondition, not part of the process
Understanding	understanding
voluntariness	voluntariness
Consent (both consent and authorization)	Consent (both consent and authorization)
Autonomy	
Relational autonomy	
"Feminist or 'relational' theories of autonomy attempt to answer the question of how internalized oppression and oppressive social conditions undermine or erode	

agents' autonomy" Stanford Encyclopedia of Philosophy	
Consent is a communicative act	
STC principles	
Localization	
Rhetoric: establish trust, alleviate fears, positive points	
Advice from community—participant's voices	
Racial concordance?	
Researcher reflexivity	
"An informed consent occurs if and only if a patient or subject, with substantial understanding, and in the absence of substantial control by others, intentionally authorizes a professional to do something" Beauchamp p. 57	"Informed consent…refers to an institutionally or legally effective authorization as determined by prevailing social rules" Beauchamp pp. 57–58

Consent is a communicative act—expand and explore

The communication must be understood by A within the social context—it must reflect values

How do Latin@ immigrants with little to no English language proficiency (negotiate) a clinical trial informed consent process?

- R1 What do Latin@ immigrants understand from the informed consent process?
- R2 Is there information important to the participants that is not being communicated?
- R3 How adequate is the structure of the conference?

Selection of study: using analogue patient methodology (reasons)—to address criticisms used a healthy patient trial

Selection of study site/participants:

This population could meet criteria of Public Health Study

Convenience sample

Parish a safe environment for this population—undocumented

Possible additional research question(s):

R4 What factors influence decisions to participate or not participate in clinical trials?

Or

R4 What factors restrict this population from participating in clinical trials?

With

R5 What factors facilitate participation in clinical trials for this participation

Note: make distinctions between (undocumented) immigrants and refugees

I found Saldaña's technique to elevate a topic from a concrete concept to the abstract extremely helpful. Saldaña (2013) recommends using what he terms the "touch test" to accomplish this conversion; "you can literally touch someone who is a mother, but you cannot physically touch the concept of 'motherhood.' You can touch an old house in poor disrepair, but you cannot touch the phenomenon of 'poverty'" (p. 249). I looked at each category and attempted to define what types of data that category contained. I used the constant comparative method of continual revision to place all data into categories until I felt there was saturation.

To explore the relationships between conceptual categories, I constructed conceptual frameworks. The initial version, created at the start of the project, is shown in Figure 3. Initial Conceptual Framework First Draft. This framework then went through several versions as I continued to compare and refine categories. Appendix R shows the evolution.

Initial Conceptual Framework First Draft

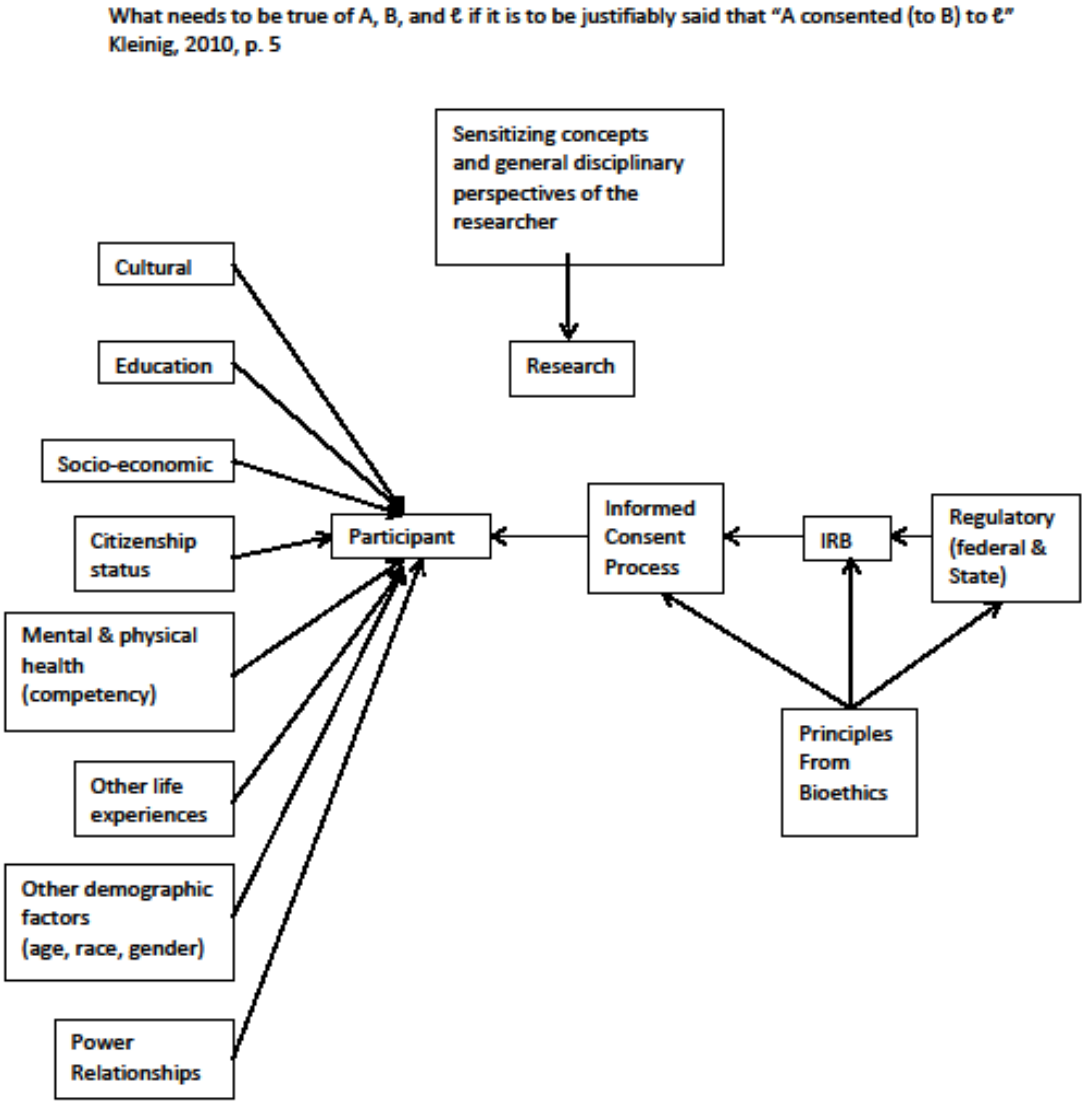


Figure 3. Initial conceptual framework—first draft

The final Study 1 conceptual framework, Figure 4., can be found at the start of Chapter 3 Discussion (p. 118) and is fully explained in the Chapter 3 Discussion. The conceptual framework was a result of writing Theoretical Memos to explore categories and the relationships between them. Table 4. Theoretical Memo Example, is an example of such a memo.

Table 4. Theoretical Memo Example

Theoretical Memo—therapeutic misconception
Should **therapeutic misconception** be a main category? Definition per Beauchamp and Childress (2009) therapeutic misconception is a problem in informed consent "where subjects may fail to distinguish between clinical care and research and may fail to understand the purpose and aim of research, thereby misconceiving their participation as therapeutic in nature" (p. 133). Therapeutic misconception renders consent invalid. Beauchamp and Childress (2009) write that Horng and Grady make a finer distinction: Therapeutic misestimation is when a participant understands "they are involved in research, rather than clinical care, [and] still overestimate the therapeutic possibilities and probabilities" (p. 134). Horng and Grady argue that as long as the participant understands possible outcomes this does not invalidate consent. Therapeutic optimism "participants accurately understand the odds that participants will benefit but are overly optimistic about their own chances of beating those odds" (p. 134). These are important to R1: What do Latino immigrants understand from the informed consent process? **Explore:** The NET-Works study materials may have set up these misconceptions. The tone of the invitation letter tone is polite and respectful, which could be seen as adhering to the Latino cultural script of *simpatía*. The study, the letter explains, "helps…families of young children." Localizing the letter may at the same time contribute to misconceptions. The participants are hearing that the researchers are concerned for them. Another example from the consent script contains appeals to the cultural values of family and community: "Your family may or may not benefit from the study, but we hope that you do. We hope you learn ways to keep your family healthy and active. We also hope that what we learn from your family will help other families in the future."

Theoretical Memo—therapeutic misconception
Examples of therapeutic misconception and misestimation can be found within the Focus Code misunderstanding/not understanding and facilitating participations (old code). Participants felt that participating in the NET-Works family would lead to a better life, "that there will more help for the Latino family to improve the lifestyle, to improve the relationship, to improve the foundation for anything in the future for the family," reading many benefits into the study that are not actually there. The notion of self-improvement was also evident, "I think that this is important for self-improvement and at the same time you're learning you're benefitting". This may be true if one is in the treatment arm. So this code is related, at times, to the understanding of randomization. Therapeutic misconception can be located along the continuum of Understanding ⟷ Misunderstanding/not understanding

The early works of Glaser and Strauss (Glaser, 1978; Strauss, 1987), called for the identification of a core category. A core category is the"central phenomenon around which all the other categories are integrated" (Strauss and Corbin, 1990, p. 116). I did not locate a core category following this definition, but rather, I adopted Charmaz' (2006) broader view of a core category. She allows that there may not be an identifiable core category and that the researcher may need to deal with several categories with a focus on making the relationships apparent. This is what is illustrated in the Study 1 conceptual framework. Finally, issues of methodological quality will be addressed in Chapter 7: Implications, Research Qualilty, Limitations, Future Research. The next section provides the results form Study 1 data gathering.

Results

Despacio voy, porque de prisa estoy

Slowly I go because I am in a hurry

In this section, I provide the gathered from a variety of sources. The first data presented are demographic data and the results of the SAHLSA -50 questionnaire, a validated instrument used to determine the health literacy of Spanish speakers. This is followed by a description of the NET-Works extant texts, which were used as the stimulus for this study. I then introduce the grounded theory resultant categories accompanied by a description of the category's content.

Demographic data and SAHLSA-50 results (n=15).

Table 5. English Fluency

	English Fluency* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 1	20%	10–>12	Too few to calculate 1 person: 36 years 2 people: 46 years	11–>25	Too few to calculate 1 person: 25 years 2 people: 11 years

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

Table 6. No English Language Skills

	No English Language Skills* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 1	40%	0–9	45	<1–20	13

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

All analogue participants completed the Demographic Data form (see Appendix H) and the Short Assessment of Health Literacy for Spanish Adults (SAHLSA -50) (see Appendix I). A complete listing of the raw data can be found in Appendix O. Since the number of participants in this research phase was relatively small (n=15), there is no statistical power in an analysis of the results. However, there are a few interesting correlations to note.

The three participants who reported speaking English fluently (with a score of 4 or 5, with 5 signifying fluent English language skills) had all received either in the range of 10–12 years of education or more than 12 years of education, all achieved high SAHLSA scores, and all had been in the U.S. for some time, two for 11–15 years and the third for >25 years.

The six participants who reported no English language proficiency all had limited formal education, ranging from no formal education to education in the range of 7–9 years. They also achieved low SAHLSA scores, including the only two inadequate

scores (inadequate defined as a score of 37 or lower out of 50). However, there were no correlations in their ages nor the number of years spent in the U.S. For example, two of these individuals reported being in the U.S. for a range of 16–20 years, while two others had arrived from Mexico just two weeks prior to their interview. For the six participants who self-rated their English proficiency as a 2 or 3 on the scale of 1–5 with 5 representing English fluency, the only similarity was achieving low SAHLSA scores. Their levels of education varied from the range of 1–6 years to >12 years, their ages varied from the 18–25 range to the 46–55 range, and the number of years in the U.S. varied from less than one year to the 16–20 years range.

NET-Works materials. As described in Chapter 3 Methods, I employed the textual materials from an actual trial as the stimuli for this study. Specifically, the materials I used were the trial invitation letter, the script used by the trial enrollers, and the consent form. Following the advice of Charmaz (2006) and Ralph, Birks, and Chapman (2014), these documents need to be situated within their contexts. The following background helps to do this.

NET-Works trial background. During data gathering in Study 1 and Study 2, I had only a cursory understanding of the actual trial, obtained from the textual artifacts and discussions with the enroller who was featured in the videos made for my study. I did this intentionally in order not to stray into interview questioning that might become more focused on trial evaluation or contain leading questions that might push participants into the "correct" answers per the original study goals. At the time of data analysis I did read an article by the NET-Works researchers describing their trial in detail. I am treating this article as an extant text along with all NET-Works textual materials I used for this study. A brief overview of the article, "NET-Works: Linking families, communities and primary care to prevent obesity in preschool-age children" is provided below in order to contextualize the materials and to better understand the comments given by those participants in this study who also happened to be participants in the actual NET-Works trial.

The NET-Works trial is part of the Childhood Obesity Prevention and Treatment Consortium. The trial looks to evaluate the efficacy of an intervention that consists of the following four parts:

> 1) a pediatric primary care brief counseling intervention; 2) a home-based intervention delivered by NET-Works family connectors to support parents in making changes in the home environment and parenting practices to promote healthful eating and activity patterns; 3) community-based parenting classes designed to parallel the home-based intervention curriculum and provide social support to participating parents; and 4) linkages to neighborhood and community resources to support parents in promoting healthful eating and activity patterns for their children (Sherwood et al. 2013, p. 545)

The NET-Works trial began trial recruitment in July 2012 and targeted December 2013 for completion. The population targeted for recruitment were racially and ethnically diverse children ages 2–4 who, among other criteria, have a body mass index greater than or equal to the 50th percentile per the Centers for Disease Control age and sex reference standards. Their caregivers were also included. The article by Sherwood, et al. (2013) contains complete descriptions of the trial design and interventions as well as their statistical data analysis plan.

Trial invitation letter. The trial invitation letter is structured as an invitation; the physician is inviting the parents of preschool children to take part in a research trial. In the NET-Works trial, the potential participant received this letter via postal mail. In my study, the participants were given a copy of this letter and were instructed to imagine they had received in the postal mail. The authors of this invitation are assuming a certain level

of literacy. The Flesch Reading ease[21] of the letter text is 56.3, with a Flesch-Kincaid grade level of 10.0.

Trial background script (verbal). (Script used for the Priming Video, see Appendix P). The enroller uses this text to provide the potential NET-Works participant trial background information. In my study, the participants receive this information via a video. The Flesch Reading ease of this text is 64.3, with the Flesch-Kincaid grade level[22] of 9.3.

The script begins by stating the trial goal: "to help kids develop healthy habits around food and activity and get ready for school" (Appendix P). It goes on to say the trial "is to help parents with young children develop positive parenting practices for healthy child growth and school readiness." The script explains the randomization by describing it "like flipping a coin." Each group (trial arm) is named and the activities associated with each group are listed. The enroller stresses that the commitment is for three years and then explains what occurs during the home visits, providing some details such as the time a visit might take. It is unclear from this explanation what makes a child eligible to be in the trial.

NET-Works consenting script (verbal). (Script used for the Consent Conference Video, see Appendix Q). The NET-Works consenting script is used verbally by the enroller to explain the Main Study Consent Form. The NET-Works potential participant listens to this explanation while consulting the form. In my study, the participants consulted the form while listening to the enroller present this script via a video. The Flesch Reading ease of this text is 64.4 versus 49.5 of the consent form. The Flesch-Kincaid grade level is 9.1 versus grade 11.1 of the Main Study Consent Form (Appendix M).

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[21] Flesch Reading ease is scored on a scale of 0–100, with low numbers corresponding to more difficult texts and high numbers corresponding to easier texts.

[22] Flesch-Kincaid grade level corresponds to the U.S. school grade of the text. Grades 13–16 represent undergraduate college level.

The enroller introduces the consent form by saying, "What we'd like to do next is walk through the Consent Form to tell you about each part of the study, get your permission to participate, and see if you have any questions" (Appendix K). The enroller is specifically saying the research group endeavors to enroll the individual into the trial. The enroller next summarizes the remainder of the information provided on the consent form. The language used in this summary is much clearer than the language used in the form. At times, it highlights the attractive aspects of the trial. For example, from the consent form,

> Your family may or may not benefit from this study. We do not know if the study activities will be helpful. That is why we are doing the study.
>
> The possible benefits of the study include learning ways to help your child develop healthy habits including eating a healthy diet and being physically active.
>
> The information we learn from this study may benefit other children in the future.

The language in the accompanying talk (from the script) stresses the research group's apparent concern for the potential participant,

> Your family may or may not benefit from the study, but we hope that you do. We hope you learn ways to keep your family healthy and active. We also hope that what we learn from your family will help other families in the future.

Main study consent form. The NET-Works consent form is something the analogue participants are reacting to as part of the stimulus and as such it is instructive to examine this extant text. The consent form is a 10-page document with a Flesch Reading ease of 49.5, and a Flesch-Kincaid grade level of 11.1. I will list each section of the trial consent form.

Background. The wording of the background section is very similar to the wording of the trial invitation letter. The stated trial purpose is "to find out if parents who receive messages and support from their primary doctor, community parenting classes, and a trained family home visitor can make can make changes at home to help their child develop healthy habits and get ready for school." (Main study consent form currently listed as Appendix M) This may imply that changes are needed. This is also a description of the intervention arm with no mention that the potential participant could be placed in the control arm where they would not take part in the parenting classes nor receive visits from the home visitor.

Procedures for participating child and adult. The procedures are listed numerically, prefaced with the statement: "If you choose to take part in the study, you will be asked to do the following" (Appendix M). However, each procedure is not worded as one might expect, in imperative form, rather it is more of a descriptor. For example, the first procedure is "Visit by trained research staff in your home to determine study eligibility." (Appendix M) The second procedure concerning measurements continues this confusing structure by introducing a list (which one assumes will be types of measurements) with "These measurements include" (Appendix M) followed by three types of measurements but then listing other activities such as a survey, interviews, wearing an Actigraph, collecting information about food and beverages, cutting a sample of the child's hair, and tasks the researchers would administer to the child.

Random assignment to study groups. This section is short and straightforward; however, the potential participant may be confused, since this is the first specific mention of being put into one of two groups.

Procedures for other family members. This is a short section, two sentences, which notes that other family members who live in the home will also be invited to participate.

Risks and benefits. This section first cautions the potential participant that they may not directly benefit from participating in this study. For those who may benefit, the potential benefits are listed. The fourth paragraph explains the risks are minimal and assures the potential participant that do not need to answer any personal questions from the doctor or family connector that they are not comfortable answering. Also, when the child is being assessed, the child may skip tasks or stop anytime they chose. This paragraph contained much more information than the other paragraphs in the document.

Compensation. This section provides the schedule for compensation. This is presented in a confusing format and uses the qualifier "up to" x amount without explanation.

Mandated reporting. This section gives a three-sentence definition of a "mandated reporter."

Confidentiality. This section provides a fairly clear explanation on how gathered information will be protected and handled. It is written using short sentences.

Voluntary nature of the study. This section is clear in describing the voluntary nature of the study.

Certificate of confidentiality. This section is clear in explaining the certificate.

Additional information about the study. This section says the "clinical trial" will be available on a government website as required by law. This is the only time in the document that the term "clinical trial" is used. It is explained that the site will not contain identifying information and the potential participant is invited to access the site, making the assumption that the potential participant has knowledge of and access to the internet.

Contacts and questions. This section provides contact information.

Categories. The grounded theory methodology I employed resulted in nine categories: Immigration Status, Effects of Working, Community's Diet/Nutrition and

Health, Education, Issues of Power and Trust, Understanding, Not Understanding/Misunderstanding, Therapeutic Misconception, and Presenting Information. A description of each category is provided in Table 7. Category Summary. The relationship between the categories will be examined fully in the Chapter 3 Discussion.

Table 7. Category Summary

Thematic Category	Datum Supporting Theme	Interpretive Summary
Immigration Status	We're very stressed about it. Because everything that's happened. The watchful groups, the immigration, the reform, police treatment, watchful groups…all of that affects the Hispanic community in one way or another. Even if you want to get near for a good cause, [the study] well now they're afraid and can't trust.	The category Immigration Status categorizes data related to the analogue participant's status as documented or undocumented immigrants, an overriding issue for many of the participants and one that affected the entire Latino community.
Effects of Working	The work and money are the ambition and results in the bad things in the home…And in this country where there's a lot of work, one can leave their family to come here to work to do things they shouldn't be. Also in video games, as Latinos work a lot and their kids are left with the video games, the crime. That's what happens to our people. We're rotting.	The category Effects of Working categorizes data describing how work is viewed and how it affects members of this community. The data shows that the participants work many jobs and this affects the family's diet, the care of the children, and may restrict participation in a trial due to time restrictions.

Thematic Category	Datum Supporting Theme	Interpretive Summary
Community's Diet/Nutrition and Health	…educate the Latino families to eat more healthy because unfortunately we are overweight, we have families with diabetes, children with diabetes, and uhm sick because they are too skinny that the children are practically anemic.	The category Community's Diet/Nutrition and Health is closely linked with the category Effects of Working in that lack of time was considered by many analogue participants as the major factor in the poor diets of many in the community. This category, Community's Diet/Nutrition and Health, categorizes data concerning the community's dietary habits and health concerns.
Education	What I think is that, you know, well, I think it will be difficult to convince someone with a lack of education to participate; you'll need a different manner to recruit.	The category Education categorizes data related to issues affected by an individual's educational level. These issues are varied; and are interrelated to items within other categories.
Issues of Power and Trust	I think Latinos; we need to see how it works to do it. We don't take those risks.	The category Issues of Power and Trust categorizes data involved with concerns about confidentiality and issues of power and trust that were sparked by the consent conference.
Understanding	That there is a group, you are looking for groups of people for some studies to help kids. What you're trying to do with us is that same thing for three years. And we'd receive	The category Understanding categorizes data that demonstrates an understanding of specific information presented during

Thematic Category	Datum Supporting Theme	Interpretive Summary
	some benefits but I think it's up to the person to decide, I think.	the trial consent conference.
Therapeutic Misconception	…there will more help for the Latino family to improve the lifestyle, to improve the relationship, to improve the foundation for anything in the future for the family.	The category Therapeutic misconception categorizes data that demonstrates what occurs when research participants believe or assume that their trial participation will provide them with the greatest possible therapeutic benefits, meeting their individual needs.
Not Understanding/ Misunderstanding	Sometimes a person doesn't understand, there were terms that I understood little.	The category Not Understanding/ Misunderstanding categorizes data that demonstrates an analogue participant is not understanding or misunderstanding the trial consent information.

Immigration status. The category Immigration Status categorizes data related to the analogue participants' status as documented or undocumented immigrants, an overriding issue for many of the participants and one that affected the entire Latino community,

> We're very stressed about it. Because everything that's happened. The watchful groups, the immigration, the reform, police treatment, watchful groups…all of that affects the Hispanic community in one way or another. Even if you want to get near for a good cause, [the study] well now they're afraid and can't trust.

Those who used fabricated social security numbers or false papers when applying for jobs had additional worries.

Being undocumented is a factor restricting participation in a clinical trial. The analogue participants were particularly wary of the mandated reporter status of the researcher. Some analogue participants said they would not participate, even if they might want to, because of the possibility they could be reported to officials and subsequently deported,

> You need the bravery to sign and provide consent because you have to know that if you're doing that, you're signing yourself to go to jail.

One reason analogue participants felt they might be reported seemed to revolve around the definition of violence. There was a belief by some that a parent who raised their voice when talking to their children was considered violent. They were concerned that if a mandated reporter heard them yelling at their children, they could be reported and at risk of deportation. This was a concern because, as one participant reported, it is common for Latinos to raise their voices,

> Well, I believe that the people from here say it is a type of violence, right? Even though it is not as such because they are not hitting them, they are only screaming at them, like, "Do this right now" or "Stop Jumping" or things like that. So then, these types of people could not participate?

Another participant explained that he had heard stories of families torn apart because someone reported domestic violence in the home,

> And not many would be interested in participating in the sense that a report to the police would be made if there was violence as the young man [the enroller on the video] commented.

Effects of working. The category Effects of Working categorizes data describing how work is viewed and how it affects members of this community. The data shows that

the participants work many jobs and this affects the care of their children and could restrict participation in a trial. Analogue participants observed that jobs are readily available in the U.S. and since only low wage work is available to them, they must work many jobs. They and went on to explain that Latinos struggle to find a balance between earning a living and being present for their families. Many of these analogue participants, both mothers and fathers, work two or three jobs including night jobs. One participant suggested that Latinos need to work twice as hard as Americans. There were many consequences for the children due to parent's time spent working, the worst case being involvement in crime,

> The work and money are the ambition and results in the bad things in the home… And in this country where there's a lot of work, one can leave their family to come here to work to do things they shouldn't be. Also in video games, as Latinos work a lot and their kids are left with the video games, the crime. That's what happens to our people. We're rotting.

One analogue participant spent some time describing, critically, the behavior of other community members with respect to their work habits and the care of their children. She commented that some allowed their children to play outside without supervision, which this participant considered a form of maltreatment,

> So I see that as a big concern for me that they don't take care of, have good caring, rearing their children and raising their children.

This same participant described how some parents ignored their children while some have commented on her daughter's attentiveness toward her. She said some children have told her,

> Well, my mom doesn't even say 'hi' to me.

Another analogue participant noted that some children prefer being with their friends rather than their family,

> That's what I see with the Latino community and they'd rather spend time with their friends because they feel better with them. That's what happens with the lack of communication within the family.

With community members spending the majority of their time working, a lack of time was cited by many as a reason not to participate in a trial,

> I think ah, ah time, time, what's, you know, what's going to be taken out of my life to participate in this study.

Others said they would want to participate in this trial, however; they did not have the time,

> I would be interested but things like the amount of time in the study, really no.

Lastly, giving precedence to work over children's diet and activities was seen as resulting in poor nutrition, sedentary behavior, and isolationism (due to playing video games or the use of other technologies),

> Uh, how should I say this? We are used to like, there are Latino people, like friends or neighbors and they have many jobs, that they do not worry about their children, they only work, work, and give no, no importance about what their children are eating.

Community's diet/nutrition and health. The category Community's Diet/Nutrition and Health is closely linked with the category Effects of Workings in that lack of time was considered by many analogue participants as the major factor in the poor diets of many in the community. This category, Community's Diet/Nutrition and Health, categorizes data concerning the community's dietary habits. The codes that are included in this category represent analogue participants' knowledge or lack of knowledge about nutrition, their eating habits, and their opinions on how these dietary habits are affecting the community's children.

Because of the lack of time, analogue participants reported regularly eating fast food or junk food, though some allowed that this was not a good practice. The comment made by one participant suggests that fast food may be considered part of acculturation,

> And I think being from a poor country we eat without eating, without knowing what we eat. And I tell my wife that now we're in a country that gives everything and we need to take advantage of it; if we're here, we need to eat the foods that are eaten here.

Several participants acknowledged they lacked knowledge about proper nutrition. One participant suggested that for some it was not necessarily the lack of time or knowledge of healthy diets, but that some did not make the time,

> To make a healthy meal. A small soup with vegetables and chicken. Place some fruit like apples or bananas on the table so the children can have them. We [indicating some community members] prefer to use our time going to the store to buy chips and soda. And that's their meal.

A participant described receiving contradictory information on which juices would be best for her children. One agency advised her to give her children apple juice, while another representative of the same agency told her apple juice contained too much sugar and is not something she should offer to her children; rather, she was advised to serve her children V-8 juice, a vegetable juice. A third representative, at a subsequent visit told her that V-8 juice was also not ideal and water was the best beverage for her children. This analogue participant along with others expressed a desire for consistent, concrete information on healthy foods, which reflected an overall concern in the community about diet and nutrition. While participants observed that many Latinos are overweight, one analogue participant noted that there are some who are underweight, again due to poor nutrition, there is a need to,

> educate the Latino families to eat healthier because unfortunately we are overweight, we have families with diabetes, children with diabetes, and

> um sick because they are too skinny that the children are practically anemic.

There were other comments concerning the community's children. One analogue participant recounted that while she made sure her child ate before leaving for school, others in the community did not. A participant expressed concern that their child's school did not allow adequate time for the children to eat their lunches. However, the school lunches, another analogue participant noted, were healthy, serving fruits and vegetables. Beneficially, some participants reported that their children were being taught healthy eating at school and some children had brought nutrition information home from school.

Referencing her family's poor dietary habits, one participant suggested that she or others might participate for the compensation and not necessarily follow trial guidelines. Though they might have healthy food in the house when a researcher is there, they might eat fast food when they are not in their home,

> But for, yes, money calls the attention of many people because unfortunately because if we are in need of money, they say, "Yes we will start the program" but like I already said, we will try to cheat and we will not simply follow it.

Related to their diet and nutrition, health concerns were among the many worries of this community,

> I'd say that there are a lot of worries for Latinos.

There were expressions of anxiety over not having a primary doctor or consistent healthcare. The community members also reported worrying about disease such as cancer and diabetes. In fact, diabetes was a frequent health topic, with analogue participants affirming the prevalence of diabetes in Mexico,

> We come from Mexico where there is a lot of diabetes.

This concern was linked to some participants requesting education on healthy eating because they had family members with diabetes. One analogue participant did say their family ate healthy because of a diabetic family member.

Education. The category Education categorizes data related to matters affected by an individual's educational level. These issues are varied and are interrelated to items within other categories. Two analogue participants noted that it is, in many ways, difficult to make generalizations about this community since members have come from different countries, arriving at different time, resulting in differing perspectives. A similar observation was made regarding the education of the community members,

> So it's a little complicated to speak general about this. Some have some education, some don't.

The data on the analogue participants reported countries of origin, years in the U.S., and education levels were reported in Chapter 3 Demographic Data.

Familiarity with technology is another factor related to education, with some participants reporting a lack of technology knowledge or a lack of internet access,

> I don't know what a website is. I think it refers to the Internet, right? I would imagine so.

One participant mentioned that the children were knowledgeable about technology, having learned about it in school.

The effects of little formal education were either directly evident or suggested in all of the categories. Within the category Presenting Information, some analogue participants indicated they had no knowledge about medical studies. Others felt they did not have an adequate education to fully understand the information provided. Within the category Effects of Working, the jobs that the participants worked were positions that required little, if any, formal education. Regarding the category Community's Diet/Nutrition and Health, many of the analogue participants stated they lacked

knowledge about a proper diet and adequate nutrition. The issues related to the category Immigration Status impede community members, and possibly their children, from furthering their formal education.

Participating in the trial was seen as a way to gain information and possibly improve the lives of the families. The focus on community and family was evident throughout all conversations in a variety of contexts. For example, one individual stated,

> More than anything, our children are the well-being of our family. I try to engage in positive activities for our family.

Improving the lives for individuals, families, or the community was given as a reason to participate in the trial,

> You know I will definitely enroll in a program that has my, that has to do with educating me and preparing me to have better children.

Another participant said that eating a healthy diet is something one could do to benefit the entire community. Several participants expressed the opinion that taking part in the trial would be important for self-improvement and was tied with creating a better life, while others pragmatically said they would participate for the monetary compensation.

Issues of power and trust. The category Issues of Power and Trust categorizes data involved with concerns about confidentiality and issues of power and trust that were sparked by the consent conference. One analogue participant stated he would want the names of the researcher's superiors because he would be wary about claims of confidentiality,

> Yeah, yeah, instead of just confidential, don't worry everything's going to be fine now. OK, you know I heard that many times and ah and ah I've been stabbed so many times when they say that.

In addition to this statement there were other comments related to issues of power and trust. For example, this same analogue participant was quite concerned about how the information gathered by the trial researchers would be used and who it might be shared with. His understanding was that the results would be released to the government. There was an element of caution in the requests for more information on visit day activities,

> I think Latinos; we need to see how it works to do it. We don't take those risks.

One component of the trial required taking a sample of the child's hair. An analogue participant stated that Americans would not allow a hair sample to be taken. Finally, a participant suggested there may be subtle pressure from the researcher to influence a possible trial participant to sign a consent form.

Understanding. The category Understanding categorizes data that demonstrates an understanding of specific information presented during the trial consent conference. The initial codes that are included in this category represent the analogue participant's assertions of understanding, which may or may not represent a correct understanding. Elements of the consent conference that the participants said they understood include various trial details, risks and benefits of the trial, randomization, and the involvement of their children.

Many of analogue participants said they were satisfied with the way the trial consent information was transmitted. While some participants indicated they understood the concept of groups (randomization), it was not clear that this was the case except for two participants, one who had studied statistics, and one who likened it to a blind date,

> Kind of like a blind date (laughter). You don't know if is going to be a pretty one.

Quite a few participants felt they understood one or more of the following points: the goals of medical research, that home visits would happen, the trial details generally, the risks and benefits of the trial, the concept of groups (randomization), and the voluntary nature of participation,

> If we want to leave, we can leave. No problem about it.

Some also felt they understood that the study involved children in one or more of the following ways; the study helps children, is about nutrition for children, teaches parents to be active with their children, or helps children to be school-ready.

Some details were less understood with only one analogue participant reporting understanding the length of the trial (three years), one participant understanding the monetary compensation for participation, and one participant understanding that the child's activities would be recorded.

***Therapeutic misconception*.** The category Therapeutic misconception categorizes data that demonstrates what occurs when research participants believe or assume that their trial participation will provide them with the greatest possible therapeutic benefits, meeting their individual needs. The initial categories that are included in this category represent analogue participants' misunderstandings of the information, categories giving reasons to participate, and categories representing the participants' beliefs regarding results of participating. Unlike other categories, aspects of the NET-Works extant materials will also be considered in this discussion.

The NET-Works trial materials may have set up some of the misconceptions. The tone of the invitation letter is polite and respectful, which could be seen as adhering to the Latino cultural script of *simpatía*. The trial, the letter explains, "helps…families of young children" (Appendix L). Localizing the letter may have contributed to misconceptions. The participants are hearing that the researchers are concerned for them. Another example from the consent script contains appeals to the cultural values of family

and community: "Your family may or may not benefit from the study, but we hope that you do. We hope you learn ways to keep your family healthy and active. We also hope that what we learn from your family will help other families in the future" (Appendix K).

Examples of therapeutic misconception are seen in the participants' comments. Some expressed the belief that participating in the NET-Works family would lead to a better life, "that there will more help for the Latino family to improve the lifestyle, to improve the relationship, to improve the foundation for anything in the future for the family", reading many benefits into the trial that are not actually there. The notion of self-improvement was also evident, "I think that this is important for self-improvement and at the same time you're learning, you're benefitting." This may be true to some extent if one is in the treatment arm, but not true of those in the control arm.

Not understanding/misunderstanding. The category Not Understanding/Misunderstanding categorizes data that demonstrates an analogue participant is not understanding or misunderstanding the trial consent information. The initial codes that are included in this category represent analogue participants' direct statements of not understanding something or represent a clear example of misunderstanding a point of the presented information. The topics of misunderstandings included terminology, trial details, trial focus, randomization, and the class topics.

Several analogue participants said they did not understand the terminology used in the presentation of study and informed consent information,

> Sometimes a person doesn't understand, there were terms that I understood little.

This is related to the comments seen in the category Presenting Information regarding the need for education to understand the trial information. Additionally, there were quite a few misunderstandings involving trial details such as what the activity device tracks, whether activity is required from the participants, the length of the trial, the benefits of

participating, the need to have a certain amount of space in your home to participate, and what benefits a participant may expect,

> and we'd receive some benefits but I think it's up to the person to decide, I think.

A common misunderstanding was that the trial was a weight loss study. Along this theme was the belief that an individual's eating would be monitored as well as a suggestion that prizes should be awarded for losing weight,

> For those people [overweight people] it will be difficult because this first day you're not going to stop eating. You have to stop gradually…but for the overweight people it will be a lot of work.

The concept of groups (randomization) was another notion that caused misunderstandings, for example, the differences between the groups. One analogue participant thought one group was a dietary plan and one group was an activity plan. Another misunderstanding was the focus of the referenced classes. There were various interpretations of this class, with participants alternatively thinking the class taught nutrition, taught parents to show interest in their children, taught parents how to create a safe place to exercise, do activities, or provide a place to do homework,

> And that um is important those types of classes that would teach us better nutrition for our children, and how to give them a space to do activities with them, like exercise as well as homework or how to show interest in your children by at least asking, "How is school going for you?"

One participant thought the classes would provide information on how to better understand the workplace,

> So it's part of the education that we need to get in order not to be abused by any company, boss; we will have more wide comprehension about what is going on in our environment.

He concluded that having knowledge is having power.

Lastly, there were perceived implications of signing the consent form, which included the idea that consent may represent an obligation to participate, or that one might be put into a medical trial (versus a well-patient trial) against their wishes. Importantly, one analogue participant observed that an understanding of the consent information may be hampered by the language difference,

> some words are said different in English and in Spanish. Some people that know English understand what the other English speaker says. But the Spanish speakers will understand it differently.

***Presenting information*.** The category Presenting Information categorizes data concerned with the process of communicating trial information during the informed consent conference. The initial categories included in this document are comments asking for additional information on a variety of topics, comments regarding education levels, and many pragmatic suggestions by the analogue participants on how best to convey the information for this trial.

The analogue participants requested additional information on a variety of topics including groups (randomization), how the trial will help their children, what will happen on the visit day, and information on cooking and healthy foods. A couple of analogue participants noted that race concordance between the researcher and the potential participants was an important consideration.

Some analogue participants indicated they had no knowledge about medical studies. Others felt they did not have an adequate education to fully understand the information provided. One analogue participant noted that Americans would not want or receive such a long consent form and explanation. This opinion is related to an observation that the audience for this trial conference must be educated people. Another analogue participant expressed concern that those without education would not participate in a trial that used this approach to present information,

> What I think is that, you know, well, I think it will be difficult to convince someone with a lack of education to participate; you'll need a different manner to recruit.

Blaming herself, one participant was apologetic for not understanding the information because she had little education,

> Well, like I said, it was understandable but I didn't study a lot and maybe that's because I didn't understand a lot of what he was saying. Maybe it was well explained for educated people, but for people like me that are less educated, like me, if he would explain it more plain or easy to understand.

This request for plain language was repeated several times when the analogue participants were offering suggestions on how to best convey the trial information to members of this community. However, it wasn't clear what "plain language" meant to the various participants. Closely related to the request for plain language was the request for an explanation that was "understandable." Similar to the use of "plain language," it was unclear what an understandable explanation would consist of. Perhaps attending to the practical suggestions listed in Table 8. may result in an "understandable" explanation. One participant felt that this trial was too complicated and the trial goals were unclear,

> I will not enroll in a program that has so many layers that you get lost and then the real meaning of what you're trying to achieve is not clear.

Shortening the length of the conference was another suggestion offered by several participants, with some suggesting that members of this community may lack the patience for lengthy explanations. Also, when talking about the length of the trial presentation, an analogue participant implied that Americans would receive a shorter presentation because they wouldn't want or need extensive information.

The participants were asked how, if they were responsible to convey the information, they would present this material to members of their community. With

respect to this specific trial, several participants suggested that the enroller should emphasize that participation would improve the family's lifestyle and future,

> So that maybe opens their mind to tell them that if you let us now to help you, your family, future, and children, they will have a better future, better everything.

There were many suggestions on how to improve the consent conference to enhance understanding by members of this community. A summary of this practical advice along with, in some cases, the reason to use the advice is shown in Table 8. Practical Advice on How to Improve the Consent Conference.

Table 8. Practical Advice on How to Improve the Consent Conference

Conduct the consent process with a group of Latinos rather than individually (Being in a group will provide participants confidence)
Send all information via postal mail prior to the meeting (Knowing the topic in advance facilitates understanding)
Incorporate former or current Latino participants to provide testimonials
Keep presentation short
Provide a strong introduction forecasting what will be covered (This will help keep people's attention)
Communicate in a direct manner
Use plain language
Focus on the main points (To prevent boredom)
Use visuals in the explanations (To accommodate those with low literacy)
Present information in sections
Confirm comprehension with exercises after each section of information
Stress that enrollers are professionals
Provide credibility by highlighting enroller's association with the University

Have a face-to-face discussion
(Allows for question and answer as well as stimulating interest and also prevents misunderstandings)

***Other information*.** Two of the analogue participants were actual participants in the NET-Works trial. They were interviewed, separately, in the context of a small focus group. While the comments of these participants and the other participants in these groups were incorporated into the data corpus, these conversations will also be discussed separately in Chapter 3 Discussion. There were also a few comments concerning my study and about myself as a researcher. These comments are provided as an inter-text on p. 225.

Conceptual Framework Study 1

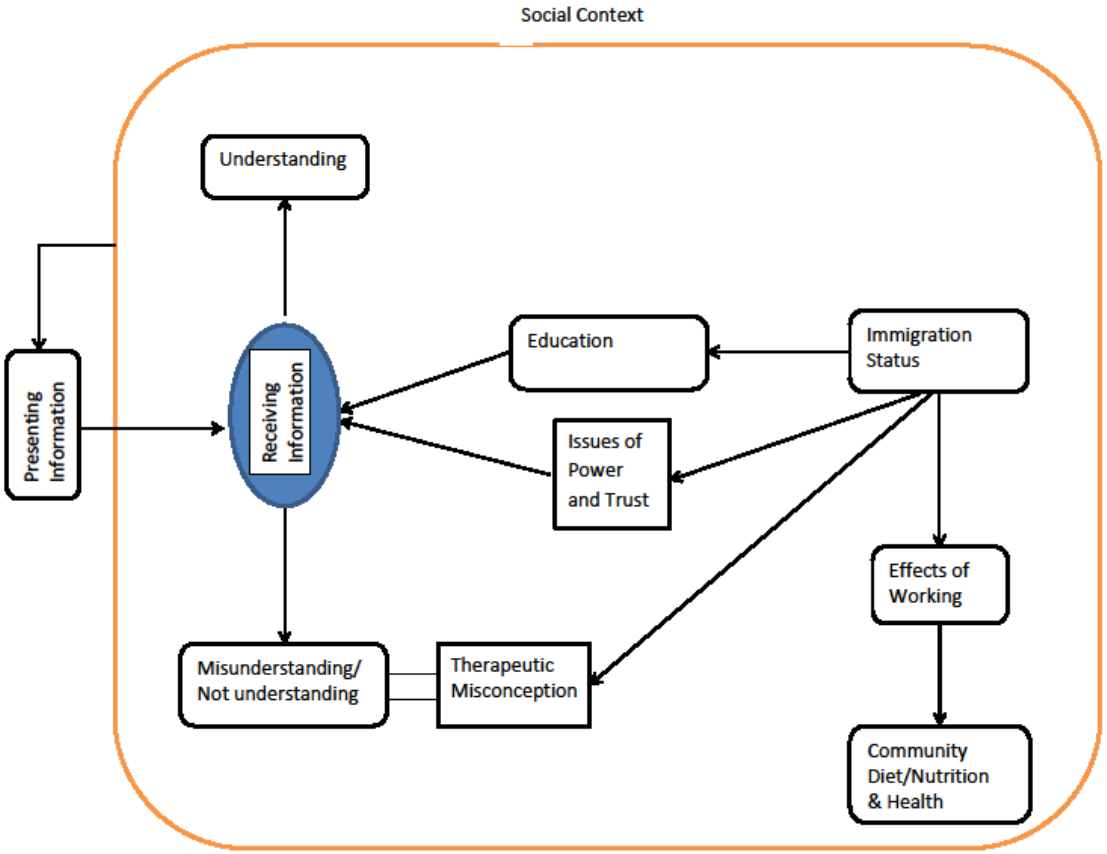

Figure 4. Conceptual framework—Study 1

Discussion

A Dios rogando y con el mazo dando

Praying to God and hitting with the hammer

As previously explained, enrollment of members of minority communities into clinical trials is important for a number of reasons. Research that includes minorities works towards the elimination of health disparities and increases the generalizability of research results. Because of this necessary inclusion, it is crucial that we understand what factors facilitate participation and what factors limit participation. It is also necessary to identify the information needs of this community, including the preferred method of communicating information. Lakes et al. (2010) notes that the "sizable recent immigrant populations in the United States require consideration of the information needs of these cultural groups and communities whose participation in biomedical and genetic research is desirable and necessary for scientific, ethical, health and social reasons" (p. 217).

This research study began with the overarching question: How do Latino immigrants with little to no English language proficiency negotiate a clinical trial informed consent process?

The data from Study 1 answers the research questions and provides relevancy and answers for two additional questions, R4 and R5.

R1: What do Latino immigrants understand from the informed consent process?

The participants in this study understood they were being invited to take part in a trial that involves their children. What is understood varies among participants. The most understood concept was the low risk of participation and the voluntary nature of participation. Least understood was the concept of randomization. Therapeutic

misconception was evident; participants perceived personal benefits that were greater than the actual possible benefits.

R2: Is there information important to the participants that is not being communicated?

Participants requested further information on trial details involving visits to their home and further qualification on the mandated reporter status of the researcher. They also requested assurances of confidentiality.

R3: How adequate is the structure of the conference?

This question is best answered by Table 8., the suggestions given by the participants on how to best present this information to Latinos. Many suggestions were pragmatic and reflect some standard usability guidelines: keep the presentation short, provide a strong introduction forecasting what will be covered, communicate in a direct manner, use plain language, focus on the main points, and use visuals in the explanations. Some advice was specific to the Latino culture: hold the consent conference in a group, prepare potential participants by sending materials in the mail, advertise in a local community paper, and have Latinos who have been or are currently enrolled in the trial attend the consent conference to provide a testimonial.

R4: What facilitates participation for this population?

Community members were interested in participating in studies that address issues that are relevant to them or their community. They looked at how they or their family might benefit from participation; at times overestimating the benefits they might

receive (therapeutic misconception). Monetary compensation was important for some, an educational component was important to most.

R5: What restricts participation for this population?

Anything that may expose a participant as undocumented restricts participation, such as the mandated reporter status of the researcher. This included a general distrust of the enroller or the trial. Research involving family was often approached cautiously. Another deterrent for this community was a lack of time due to work responsibilities. Finally, lack of education can interfere with understanding.

This section will explicate the grounded theory by describing the participant's social context, the effect of this context on the participants' autonomy, and an approach to informed consent that works to overcome diminished autonomy and meet cultural needs. Rhetorical principles help explain the therapeutic misconceptions.

The bioethical ideal of informed consent is based on an autonomous individual receiving relevant information, comprehending it, and agreeing or declining to participate. I am arguing that the consent process has a persuasive component, tempered by autonomy. The process includes the researcher being satisfied that her trial design is ethical, with the risks and benefits thoroughly considered, and the additional safeguard of review and acceptance by the appropriate institutional IRB. The consent conference then has goals of presenting prescribed information in an understandable manner, per IRB guidelines, and inviting the potential participant to join the trial, while demonstrating a respect for autonomy. Sherwin (1998), discussing autonomy noted,

The paradigm offered for informed consent is built on a model of articulate, intelligent patients who are accustomed to making decisions

about the course of their lives and who possess the resources necessary to allow them a range of options to choose among (p. 24).

Felt et al. (2009) observed that research participants don't necessarily make decisions based on the information formally presented, but also, or even solely, based on other resources, such as their social context. The social context of the participants in this study will be outlined and illustrated in the following subsection. Refer to Fig 4. located at the start of this Discussion section (p. 118) for the conceptual framework that visually displays the grounded theory categories that make up the social context and the consent conference and demonstrates their connections. The social context as well as reactions to the consent conference will be discussed using these categories.

Social context. The social context of this study's participants is rich, complicated, historically bounded, and multilayered. Interwoven are the community's attributes of immigration status, English-language ability, ability to balance work and family care, nutrition, levels of physical activity, health concerns, education levels, and issues of power and trust. The participants experience these attributes and their combinations to varying degrees.

Historical context. Data from this study builds a framework of the social context from which members of this community understand information and make decisions. This context is historical, grounded in the date and place of this study. The historical context, explained in Chapter 3, was the following: Nationally, President Obama had deported more than 1.9 million foreigners since taking office in 2009, a record number for any one president. According to the Pew Hispanic Center, the Obama administration had deported nearly 400,000 unauthorized immigrants annually between 2009 and 2012 ("Public divided over increased deportation of unauthorized immigrants," 2014). During fiscal year 2013, 368,000 people were deported (Preston, 2014, para. 7).

Locally, the city office of the U.S. Immigration and Customs Enforcement had conducted a raid at three locations of a Spanish immersion day care chain during the

summer months of 2013, causing the departure of approximately 60 teachers and workers—40% of the entire staff (Brunswick, 2013). The school spokesman told a reporter that "employees have passed a series of background checks—including the federal verification and a state Department of Human Services (DHS) background check required for all day-care workers—and a separate check of references, education certificates and past employment conducted by the day care's owners" (Brunswick, 2013, abstract). However, the state criminal background check does not examine immigration status.

Immigration status. The conceptual framework (Fig 4.) provided at the beginning of this section (p. 118) illustrates the dynamic, complex condition of the participant's lives per their descriptions. It is important that the reader note that the topics of the public health trial used for the simulation—children's diet, activity and school readiness—stimulated the interview discussions in those directions, however, the conversations were candid and genuine, leading to a description of various challenges within the community. The most significant factor within this social context is an individual's immigration status. An undocumented status touches all aspects of an individual's life affecting, for example, what jobs they can work, their level of education, and what they chose to participate in, including participating in a study or trial.

The Pew Research Center reports 11.2 million unauthorized immigrants in the U.S. in 2012, with 52% from Mexico (Passel & Cohn, 2013). To the participants in this study, the majority being from Mexico, jobs in the U.S. seem plentiful. However, due to the undocumented status of many participants, their lack of English language skills, and often, a low level of formal education, most of the jobs that are available to them are for unskilled labor and offer, to an American viewpoint, a low wage. It is not uncommon for falsified documents to be used in order to secure a job. The opportunity to earn, what is to this community, a meaningful amount of money has resulted in many community members working two or even three jobs. The money is used for the care of their nuclear families and a portion is often sent to relatives in their country of origin.

While the majority of participants report being in the U.S. for anywhere from 10 to 25 years, only three (20%) report speaking English fluently or almost fluently. This very small sample size carries no statistical weight. However, the Pew Research Center's statistics on the English-speaking ability of Hispanics ages 18 years or older who have been in the U.S. since 2000 are statistically valid and report that 30.9% of these foreign-born Hispanics report speaking English "less than very well." This lack of language proficiency limits employment opportunities and contributes to community isolation. One participant summarizes,

> Because in all honesty, Latinos are just a little closed off.

This lack of English-language ability after a decade or two of living in the U.S. is a complex phenomenon of which a full examination is beyond the scope of this discussion. Anzaldúa (1999) reflected on this condition,

> Chicanos and other people of color suffer economically for not acculturating. This voluntary (yet forced) alienation makes for psychological conflict, a kind of dual identity—we don't identify with the Anglo-American cultural values and we don't totally identify with the Mexican cultural values. We are a synergy of two cultures with various degrees of Mexicanness or Angloness. I have so internalized the borderland conflict that sometimes I feel like one cancels out the other and we are zero, nothing, no one. *A veces no soy nada ni nadie. Pero hasta cuando no lo soy, lo soy* (p. 85) [Sometimes I am nothing and nobody. But even when I'm not, so I am.]

Anzaldúa observed that the way one speaks forms an integral part of identity. Whiteside (2006) called for further research on "the impact of legal status on language practices" (p. 105) and speculated that an undocumented status may, in effect, erode one's right to speak, in order to not draw attention to oneself.

Effects of working. Participants described difficulties balancing work responsibilities and caring for their families. With both parents working multiple jobs, there was little time available for them to help their children with their homework, encourage and facilitate physical activities, supervise the children, and maintain a healthy diet. One participant explained,

> Latinos, we do not have the ahh we do not have a paycheck that guarantees our comfort living, so we have to work twice as hard and that limits our time, even with the family, we don't have time for the family because we're struggling to make that money for the bills, the rent.

The Pew Research Center reports that 1 in 20 people in the 2012 U.S. workforce, 8.1 million people, were unauthorized immigrants ("Testimony of Jeffrey S. Passel," 2015). Another participant described the effects of working many jobs this way,

> Um, how should I say this, we are used to like, there are Latino people like friends, or neighbors and they have many jobs that they do not worry about their children, they only work, work, and give none, no importance about what their children are eating, how are they are eating, if they are in activities.

The results from a study by Nobari et al. (2013) suggested that immigrants living in neighborhoods where the residents speak the same language (other than English) may influence obesity-related behaviors of diet and physical activities. Similarly, participants from this study allowed that parents' time spent working did result in poor diet, sedentary behavior, and isolationism (due to playing video games or the use of other technologies). A participant illustrated this point,

> that is the bad things that technology brings too is the isolationism and the, what they call sendentarianism, you know, where you just, you just stay sedentary you know, you don't move, playing, texting, yeah all that has to do with just a keyboard, just sit in a bubble.

Worse than not encouraging physical activity, inattention to the children can result in a child becoming involved with criminal activities. A participant described the situation this way,

> Someone wants to work, and work and work, and they stop doing the things that are good for them. The work and money are the ambition and results in the bad things in the home. Many Latinos, they go to work and then bring Sabritas to their kids. They give them bad nutrition. And in this country where there's a lot of work, one can leave their family to come here to work, to do things they shouldn't be. Also in video games, as Latinos work a lot and their kids are left with the video games—the crime. That's what happens to our people. We're rotting.

The traditional cultural construct of *familismo* seems to have been shaken under the stresses caused by immigration and for many, their undocumented status. I asked the priest from the church where Study 2 took place about the above comment. He corroborated this statement writing,

> The comment is sad but true. Because of working so much and so hard child supervision suffers (personal communication, August, 5, 2014).

While speculating about what is happening within these immigrant families, I asked this priest and the parish mental health provider this question: To your knowledge do many families with children have extended families here with them—aunts, uncles, and specifically grandparents? The parish mental health provider replied,

> I imagine that there are not a lot of reliable demographics out there….The reality of family movement is quite complicated (personal communication, August, 5, 2014).

According to Andrés-Hyman, Ortiz, Añez, Paris, and Davidson (2006) *familismo* is an "allocentric cultural value that stresses attachments, reciprocity, and loyalty" (p. 696) to the immediate and extended family, including close family friends.

Traditional families live in a patriarchal arrangement and follow traditional gender roles. The children are taught to accept the family as a central focus of their lives (Hancock, 2005). In the immigrant families in this study both parents often work, causing a disruption in a traditional family structure without, perhaps, a clear way to negotiate this new reality. A participant noted a consequence of this disruption,

> That's what I see with the Latino community, they'd [community's children] rather spend time with their friends because they feel better with them. That's what happens with the lack of communication within the family.

This move away from tradition may be partially explained by this observation from Jandt and Tanno (2001) "all colonized, oppressed, and marginalized groups have…been foreshadowers of fragmentation because they have always known anomie[23] and always had their identities wrested from them" (p. 130). The previously noted participant's comment, "We're rotting," seems to hint at this. Anzaldúa's (1999) description (page 126) of the feeling immigrants experience of being torn between the two cultures of Mexico and the U.S. provides further insight into a disruption of the traditional family.

Another consequence of so much of the particiants' time spent working, already mentioned, is a poor family diet. Lack of time to prepare a nutritious meal was often mentioned, with fast food being used as a convenience. However, others felt they didn't have adequate or correct knowledge about nutrition and would like a way to learn about healthy foods and healthy cooking,

> Like I was saying to educate them, educate the Latino families to eat more healthy because unfortunately we are overweight, we have families

[23] Anomie, a term originally introduced by Durkheim, is defined by the Oxford dictionaries as the "lack of the usual social or ethical standards in an individual or group" (http://www.oxforddictionaries.com/us/definition/american_english/anomie)

> with diabetes, children with diabetes, and uhm sick because they are too skinny that the children are practically anemic.

Community's diet/nutrition and health. One way to learn about proper nutrition was through the community's school-age children. One participant remarked approvingly that the school was serving healthy lunches, including fruits and vegetables. Others reported that their children were being taught how to eat in a healthy manner at school and there are some children who had brought nutritional information home from school. It is curious that these participants were not accessing local knowledge of their traditional diet. Perhaps poverty limited their diets in Mexico or perhaps they were attempting to use food as an element of acculturation. This comment speaks to why traditional diets are not being followed,

> I think that being from a poor country we eat without knowing what we eat. And I tell my wife that now we're in a country that gives everything and we need to take advantage of it if we're here, we need to eat the foods that are eaten here.

Related to concerns about diet and nutrition, the participants of this study expressed health concerns, especially concerning cancer and diabetes.

I did not collect information on whether the participants had health insurance or dependable healthcare, however, a lack of available or regular healthcare could contribute to these concerns,

> There are a lot of worries for Latinos. Us Latinos don't watch what we eat. We eat what we want; we have a propensity for diabetes; cancer; we worry a lot.

Latinos do, in fact, have a higher rate of diabetes (12.8%), than non-Hispanic whites (7.6%). Realizing that the Latinos in the U.S. come from a variety of countries

and that the participants of this study are primarily Mexican, it is instructive to look at a breakdown of that 12.8%:

8.5% Central and South Americans
9.3% Cubans
13.9% Mexican Americans
14.8% Puerto Ricans

("Statistics about diabetes," 2014)
(Note: all but one participant in Study 1 was from Mexico)

New immigrants have the same cancer risks as they had in their home country, however, acculturation eventually moves that risk to equal to that of Americans. For example, the American Cancer Society reports the incidence of colon cancer among Mexicans living in Florida is more than twice that of Mexicans living in Mexico. Overall, Latinos have a lower risk than non-Hispanics whites or blacks for the most common cancers except for cervical cancer, where Latinas have a 60% higher risk that non-Hispanic whites ("Cancer Statistics about Hispanics Released," p. 2012).

Education. An individual's level of formal education is another key determinant of their lifestyle. Roughly half of the participants in this study reported having completed 12 years of education (with two individuals reporting 13 years), the other half reported having anywhere from no formal education up to nine years of education. A participant described the situation this way,

> a lot of people don't' even know how to read, write, or understand. They won't have the education to understand this. And some didn't even go to school. So it's a little complicated to speak generally about this. Some have some education, some don't.

An undocumented status hinders attempts at furthering an education in any number of ways. The Pew Research Center reports that, as of 2012, of foreign born

Mexicans, 39.2% had less than a 9th grade education and 23.5% had completed high school ("Statistical Portrait of the Foreign-Born Population," 2012). This is directly applicable to the informed consent process in that the reading level of the consent documents may hinder understanding. In Chapter 3 Results, I reported the reading levels of the textual artifacts used in this study. The introductory letter has a Flesch-Kincaid grade level of 10.0, the background script (verbal) has a Flesch-Kincaid grade level of 9.3, the Main Consent Form has a Flesch-Kincaid grade level of 11.1, and the consent script (verbal) has a Flesch-Kincaid grade level of 9.1. Tatiana Batova (2010) noted, "readability studies suggest that the reading level for informed consent documents should be between 5th and 10th grade" (p. 275).

The educational level is also related to knowledge of and access to technology. The community's children not only acquired knowledge about nutrition in school, they also acquired technological knowledge. It is unclear from this data if and how this information is passed on to other family or community members. A comment from one participant illustrated a technology divide,

> I don't know what a website is. I think it refers to the internet, right? I would imagine it so…Sometimes my kids tell me, send him an email or a text and they laugh at me because I don't know what it is. Then they laugh when I ask how or what it is. They studied a little bit and that's how they laugh at me!"

Issues of power and trust. Finally, and importantly, are those issues involving power and trust. Most of these issues were rooted in fears of deportation. Examples of concerns were seen in the participant's reactions to the NET-Works trial, which included worrying about how the information gathered by the researchers would be used and who it might be shared with. This concern about confidentiality is reflected in this comment,

> Yeah, yeah, instead of just confidential, don't worry, everything's going to be fine now. O.K., you know I heard that many times and ah and ah I've been stabbed so many times when they say that.

Lakes et al. (2010) found similar perceived risks associated with privacy and security. Another participant in this study asked for additional information for this reason,

> I think Latinos; we need to see how it works to do it. We don't take those risks.

Additionally, there was considerable wariness surrounding the mandated reporter status of the NET-Works trial researcher. Some participants said they would not participate in the NET-works trial, even if they might want to, because of the possibility they could be reported to officials and subsequently deported,

> you need the bravery to sign and provide consent because you have to know that if you're doing that, you're signing yourself to go to jail.

One reason analogue participants felt they might be reported seemed to revolve around the definition of violence. There was a belief by some that parents who raise their voices when addressing their children was considered violent in the U.S. They were concerned that if a mandated reporter heard them yelling at their children, they would be reported and at risk of deportation. This was a concern because, as one participant reported, it is common for Latinos to raise their voices,

> well, I believe that the people from here say it is a type of violence, right? Even though it is not as such because they are not hitting them, they are only screaming at them, like, "Do this right now" or "Stop Jumping" or things like that. So then, these types of people could not participate?

Another participant explained that he had heard stories of families torn apart because someone reported domestic violence in the home,

> And not many would be interested in participating in the sense that a report to the police would be made if there was violence as the young man [the enroller on the video] commented.

The qualifications of the mandated reporter were also questioned,

> I've seen families you know that have been victims of this of um of this concentrations. So yeah so how you know who's going to tell are they qualified to to identify because it is their obligation. Yea so they might not do the right evaluation and get someone in trouble then destroy the family for the rest of their lives.

The inter-text story that preceded this chapter also illustrated deep-seated mistrust. This participant equated being recruited into a trial to being recruited into the Navy and highlighted issues of misrepresentation and racism.

Autonomy—constraints of the social context. I invite the reader to review the subsection on autonomy in Chapter 2 beginning on page 39 for a full discussion of the second tenet of the principle of respect for persons in the *Belmont Report*, which states that "persons with diminished autonomy are entitled to protection" (Belmont Report, 1979, Part B. 1., para. 1). In fact, some groups or individuals may be prohibited from participating in experimentation. Determining the extent of protection should depend on the level of risk and the likelihood of benefit (Part B. 1., para. 4).

1. Information: This element describes what sort of information should be provided. The items generally included are descriptions of the procedure, purposes, risks and benefits, and alternative procedures. Additionally, subjects are given the opportunity to ask questions and the opportunity to withdraw from the research.
2. Comprehension: This element includes issues of the adaptation of the information and allows special provisions for those who may have limited comprehension.
3. Voluntariness: This element includes issues of coercion.

Gillies and Entwistle (2012) pointed out that personal autonomy can mean something different than the traditional understanding of the term if "we take seriously

the profound ways in which social and cultural environments and networks of relationships influence how people can and want to shape their individual lives" (p. 753). Sherwin (1998) used a feminist perspective to offer an alternative view of autonomy, a relational approach that "allows us to maintain a central place for autonomy within bioethics, but…requires an interpretation that is both deeper and more complicated than the traditional conception acknowledges" (p. 44). This approach can be thought of as 'socially situated' or 'contextualized'; I am calling this 'social context.' Sherwin (1998) explained her concept of relational autonomy as a "relational conception of personhood that recognizes the importance of social forces in shaping each person's identity, development, and aspirations" (p. 35).

It is important at this point to revisit the following discussion on relational autonomy as explained in Chapter 2 before looking at the data related to this concept. McLeod and Sherwin (2000) extended the discussion of relational autonomy by focusing on how oppression obstructs autonomy; it "functions in complex and often largely invisible ways, affecting whole social groups rather than simply disrupting isolated individuals; as a result, its effects tend to be ignored within the traditional autonomy framework that focuses solely on individuals" (p. 259). The authors nuanced the effects of oppression by noting that individual members of oppressed groups are affected in individual degrees and, by belonging to more than one group (e.g., through minority status, gender, or education level), an individual may be privileged in some areas, while oppressed in others. Notably, they reminded us that those experiencing oppression are not necessarily incapable of exercising autonomy. McLeod and Sherwin (2000) explored the effect oppression has a person's self-trust and argued that a degree of self-trust is a necessary prerequisite to autonomy, saying "[an][a]gent must trust her capacity to make appropriate choices, given her beliefs, desires, and values; that she trust her ability to act on her decisions; and also that she trust the judgments she makes that underlie those decisions" (p. 263).

The social context explained in the previous subsection situated this community within their social and cultural environment. Relationship networks can be inferred, beginning with family units and reaching out within the community. This social context directly defined their autonomy. The greatest oppression these community members experienced is an undocumented status. This effectively kept individuals in constant fear of deportation. The stress of this possibility increased for those families with children who are American citizens, fearing that the family could potentially be torn apart. Additionally, low levels of formal education coupled by low English language skills positioned individuals in a semi-permanent socio-economic state, with their only option to work longer and harder for economic stability.

It is necessary to recognize that each individual will experience oppression in varying degrees within different areas of their lives; nonetheless, persons experiencing oppression are not necessarily incapable of exercising autonomy. I will address how best to present information to ensure the greatest level of individual autonomy in the subsection of this chapter titled "Presenting information."

Receiving information. In this study, participants spoke about the role their level of education played in receiving the trial information. Some participants felt that those with a low formal education level would not agree to participate in the presented trial due to difficulties in understanding the trial details. When one participant was asked if she feels, in general, that this community would understanding the terms used in the consent conference she replied,

> Well, I don't think so. No. Like I said before, depending on the group or education they have. A lot of people don't even how to read, write, or understand. They won't have the education to understand this. And some didn't even go to school.

Fig 4 (p. 118) visually shows how the analogue participants hear the presented information through the screen of their social context and understand it somewhere along

a continuum between complete understanding and misunderstanding or not understanding.

As explained in Chapter 3 Results, the category Understanding represents the analogue participants' assertions of understanding, which may or may not represent a correct understanding of the information. Different participants claimed to understand various parts of the information such as trial details, risks, and benefits of the trial, randomization, and the involvement of their children in the trial. The concept of randomization seemed to be the least understood concept, with only two instances of confirmed understanding. One analogue participant who understood the concept was well educated and said she had taken a course on statistics so the concept was clear to her. Another participant demonstrated understanding of the concept through metaphor,

> Kind of like a blind date (laughter). You don't know if is going to be a pretty one.

The concepts grasped by most of the participants were the voluntary nature of participation and the low risk of involvement,

> Well, I understood it all. About the benefits and the risks. A small risk is all…And when we sign, if we want to leave, we can leave. No problem about it.

At times it was clear that even though participants asserted understanding, they had misunderstood or they did not retain the information. For example, one participant said,

> You know what, it seems like everything he [the enroller in the video] said is fine.

At another point in the interview the same participant said, in response to a query asking if there is anything about the trial she did not like,

> It's all fine, what the man [the enroller in the video] said.

However, when asked what she remembered about the discussion on the randomization of study participants she could not recall anything. When asked how long the study lasted (three years), the participant responded,

> One hour.

Similar to the results presented here, Tait, Voepel-Lewis, Malviya, and Philipson (2005), in a study testing a modified consent document for readability and processability, found that most participants *overestimated* [emphasis added] their understanding of the information presented in the document. One explanation for these assertions of understanding and assertions of satisfaction on how the information was presented is rooted in the concept of *simpatía* as conceived by Triandis, Lisansky, Marín, and Betancourt (1984). They discuss this term, which they call the cultural script of Latinos, explaining that *simpatía* refers to aspects of one's personality that allow others to perceive an individual "as likable, attractive, fun to be with, and easygoing" (p. 1363). An individual who is *simpatico* displays empathy and "behaves with dignity and respect toward others, and seems to strive for harmony in interpersonal relations" (p. 1363). The avoidance of negative behaviors is rooted in the cultural values of *respeto* (respect) and *dignidad* (worthiness). Therefore, to remain polite and respectful, a participant might indeed say the presentation was satisfactory and that they understood the information. In the following statement a participant said the explanation was understandable while blaming her own lack of education on not being able to understand,

> Well, like I said, it was understandable but I didn't study a lot and maybe that is why I didn't understand a lot of what he was saying. Maybe it was well explained for educated people but for people like me, that has less education, like me, if he would explain it more plain or easy to understand.

An interesting situation occurred when I interviewed, separately, two people who had been recruited into the actual NET-works trial. The first participant was interviewed within a group of four people. Though recruited, this woman did not subsequently enroll in the NET-Works trial because her child would not wear the activity belt, which was compulsory. During the focus group interview this participant took the lead in the discussion. Since she had actually been recruited she was treated as the important person in the group, with the other members giving her deference and agreeing with her statements. This analogue participant maintained throughout the interview that she understood all the information that had been presented. When asked about randomization she said,

> I understood about the two groups, they would be divided into two parts because there would be families. So divide 250 into each group. And in what group it would be, it would be in house or by telephone.

She was correct that each trial arm would have 250 people. However, the difference between the groups, per the NET-Works main consent form is:

- NET-Works group: Families in this group will take part in monthly community parenting classes, home visits, and phone calls each year of the three-year program to talk about healthy eating, activity, and parenting. Each of the sessions will be audio taped for evaluation purposes.
- Comparison group: Families in this group will follow their usual schedule of medical visits. They will not receive the additional phone calls, home visits, or community parenting classes (Appendix M, p. 331).

The second participant who had been recruited into the actual NET-Works trial was part of a group of three people. As with the woman just discussed, this woman maintained she understood all the information presented both at her home and in the videos and was satisfied with the manner in which it was transmitted. It was clear that

she did understand the randomization aspect of the trial. The conversation from this group was quite interesting. Since one of their group had, or still was, participating in the actual trial, the other group members were approving of the program. In fact, they felt taking part would lead to "a better life." They also talked about how important children were to the community's families. One group member mentioned that she would like to learn nutritional information by participating in this program,

> But also…I know what is good and bad to eat, what we should eat that isn't bad for us but I'd like for them to tell us which foods are healthy and unhealthy. We know but we forget.

Another group member responded to her,

> I heard from [name of actual participant] that they didn't tell her anything of that.

There is some question whether the women who had actually been recruited understood everything in the videos as asserted or if there was some degree of "recognition" that was being labeled as "understanding." Another form of misunderstanding is therapeutic misconception, which was displayed by many participants.

Therapeutic misconception—a better life. Therapeutic misconception occurs when a research participant believes "that their individual needs will determine treatment, or that the likelihood of benefit is greater than is actually the case" (Candilis & Lidz, 2010, p.338). The implications of therapeutic misconceptions are significant in that they effectively exclude an authentic informed consent. I will begin this discussion by looking at the NET-Works materials that were used as the stimulus for this study. These materials, the invitation letter, the trial background script, the NET-Works consenting script, and the main trial consent form were described in Chapter 3 Results. Though the wording of these extant texts was relatively neutral, they may be partially responsible for some of the misconceptions seen in some of the participants' comments.

In the trial invitation letter, the status of the physician, as well as the status of the other researchers who are also signatories, provide an authoritative *êthos*. The tone is polite and respectful, which could be seen as adhering to the Latino cultural script of *simpatía*. The study, the letter explains, "helps…families of young children develop positive parenting practices for healthy child growth and school readiness." The family and the children are a central focus for this culture, so the topic would be seen as important. The apparent willingness to help implies a concern for the individual and their families. The letter does make the voluntary nature of participation clear, by using the genre of an invitation, by using the phrase "if you join," and by clearly stating "Taking part in this study is voluntary."

On the other hand, by inviting one to take part in a trial that helps families develop positive parenting practices could imply that those skills are currently lacking. An additional issue is the fact that this is a two-arm trial, with the intervention group receiving parenting classes, phone calls, and home visits. This is not explained and the wording regarding the intervention arm is ambiguous, "You may also get to participate in". This ambiguity can contribute to participants' therapeutic misconceptions. Finally, the fact that the invitation recipient must be proactive and contact the trial staff if they not want to participate may be considered an unusual opt-out process and as such might be confusing to the potential participant.

The NET-Works invitation letter, as mentioned, was sent by the physician who cares for the child, researchers associated with the university, and a medical research foundation; these are all people in positions of power. Though the analogue participants showed they would approach entering a trial with caution and wariness, there was a certain level of trust given to the researchers in the simulation due to their status. With this trust was an assumption that the researchers would promote their health and the health of their families and community. This contributed to therapeutic misconception.

Hofstede (1980) identified Power Distance as one of the value dimensions that describe culture. This dimension is high for Mexico and Latin America and refers to the level of acceptance of an unequitable distribution of power and wealth. The result is that less powerful members of the society accept a hierarchical order without question. This may explain, culturally, why the researchers were awarded a certain amount of trust. Another assumption that may be described culturally is the reception, by the analogue participants, of the invitation letter. As noted previously in Chapter 3 Results, the tone of the invitation letter is polite and respectful, which could be seen as adhering to the Latino cultural script of *simpatía*. The trial, the letter explains, "helps…families of young children." From this the participants might have been hearing that the researchers are concerned for them.

By contrasting what is written in the consent form and how this information is summarized verbally by the enroller, one can see potential differences in meaning. In the likelihood that a potential participant is illiterate, the consent form would be explained to them rather than read by them. The second woman who had been enrolled in the actual NET-Works study said she was not given the consent form,

> The man, he was reading it to me and asking me questions if I was in agreement. Or if I didn't understand.

It wasn't clear if the enroller read from the actual consent form or the verbal consent script.

> Consent Form: You are invited to take part in a research study about helping families with young children make healthy choices that will last a lifetime. The purpose of the study is to find out if parents who receive messages and support from their primary doctor, community parenting classes, and a trained family home visitor can make changes at home to help their child develop healthy habits and get ready for school.

> Verbal Consent Script: What we'd like to do next is walk through the Consent Form to tell you about each part of the study, get your permission to participate, and see if you have any questions. First, the purpose of this study is to find out if the two NET-Works programs we offer help parents with two–four year-old children make changes at home to help their kids develop healthy habits and get ready for school.

It is not explicated in either of these versions that there are two trial arms with only one of the trial arms offering parenting classes. In both explanations, participation appears to provide helpful support for the parents.

There is a significant difference between the following section of the consent form and the verbal consent script,

> Consent Form: Your family may or may not benefit from this study. We do not know if the study activities will be helpful. That is why we are doing the study. The possible benefits of the study include learning ways to help your child develop healthy habits including eating a healthy diet and being physically active. The information we learn from this study may benefit other children in the future.

> Verbal Consent Script: Your family may or may not benefit from the study, but we hope that you do. We hope you learn ways to keep your family healthy and active. We also hope that what we learn from your family will help other families in the future.

The participants were hearing that the researchers are hopeful that they, the potential participant, have the best possible experience.

In the case of this study, the participants exhibited therapeutic misconception not by thinking they would receive superior medical treatment. Rather, many participants expressed the belief that participation would lead to "a better life," possibly improving

the family's lifestyle and future. There is evidence that participants believed participating in the trial would directly benefit them and their families to an extent that was not being offered. Examples of this include,

> It's [the NET-Works study] very interesting and good to try to improve our lives.

> [With respect to the consent script shown on the video] I would put more emphasis that there will be more help for the Latino family to improve the lifestyle, to improve the foundation for anything in the future for the family.

> I think that this is important for self-improvement and at the same time you're learning, you're benefitting.

Several participants misunderstood the trial to be a weight loss trial, which might help them become healthier,

> It was all clear. I understood that it will all be about your activity. I think the device they'll give you will track what you eat and if you're a little overweight you'll have to be active.

Another manifestation of therapeutic misconception was the assumption that the participant would be taking the parenting classes. This was true whether the participant understood that these classes were only provided in one arm of the trial or if they thought they were provided for all participants,

> And that, um, is important, those types of classes that would teach us better nutrition of our children, and how to give them a space, a space to do activities with them, like exercise as well as homework, or how to show interest in your children by at least asking, "How is school going for you?"

These misconceptions are similar to those found in a study done by Lakes et al. (2010). That study involved recruiting 53 women of various ethnic backgrounds to comment on the recruitment strategies of the National Children's Study (NCS), a genetic

research study. The NCS study was a multi-site, observational, longitudinal (birth to age 21), and community-based project that examined the effects of environmental and genetic influences on the health and development of more than 100,000 persons across the U.S. The study by Lakes et al. (2010) is similar to this one in that the participants were not being enrolled into an actual trial. To examine their data these researchers used qualitative thematic methods, which they described as a methodology using both pre-determined codes and grounded theory. Under their identified theme[24] Perceived Benefits Associated with Participation, they observed, "During some focus groups, particularly with Latinas, participants expressed an assumption that results would be used to develop programs and services that would help children" (p. 225). Under the identified theme of Information Needed to Make a Decision, they observed, "Latino participants described expectation of research participation…that were similar to expectations one might have of a social service program" (p. 225). Lakes et al. (2010) consistently found that the Latino participants expected the personal benefits realized by trial participation exceeded the actual possible benefits and that these personal benefits "would be similar to participation in a social service program" (p. 227). This form of therapeutic misconception linking participation to personal or familial benefits that were similar to a social service program was also evident in this study's data.

A rhetorical account. There is clear evidence of therapeutic misconception in this study's data. The therapeutic misconception exhibited is the perception that trial participation has the potential to improve a family's lifestyle and potentially their future. Some believed that they would attend classes and be taught skills they had self-identified, even if those topics had not been mentioned. There was also the belief that participation could lead to 'a better life.'

The concept of *identification* provides a technique, an approach, to examine and explain the analogue participant's reactions to the simulated consent conference.

[24] *Themes* are similar to *Categories* in this study.

Kenneth Burke (1969) remarked, "You persuade a man only insofar as you can talk his language by speech, gesture, tonality, order, image, attitude, idea, *identifying* your ways with his" (p. 55). Graff and Winn 2011) explained the development of this concept and stressed that "a full understanding of Burkeian Identification requires consideration of its appearances in works prior to its elevation to the status of 'key term' in *A Rhetoric of Motives*" (p. 106).[25] Burke discusses Identification in his 1930s and early 1940s writings, however the concept wasn't given prominence until his 1969 work, *A Rhetoric of Motives*. In this book, Burke fully explained Identification, situating it as a supplement to classical rhetorical theory. Identification, Burke said is a necessary element in human communication in that it is a necessary corrective for the naturally occurring process of human division. Burke (1969) explains, "Identification is affirmed with earnestness precisely because there is division. Identification is compensatory to division. If men were not apart from one another, there would be no need for the rhetorician to proclaim their unity" (p. 22). To rise above division, one seeks attributes, for example, interests and values that an individual may have in common with others.

It is not clear to me what localization efforts were employed in the preparation of the consent textual artifacts other than translation into Spanish. There was no mention of tailoring the materials to a specific population or whether they employed a recruitment approach for specific ethnic populations in the original researcher's article describing the trial (Sherwood et al., 2013). Nevertheless, the participants perceived that the researchers were identifying with them because the topics of the trial used in the simulation were topics that held deep importance for them: their children, their diets, and their health. The values this community ascribed to these topics contributed to the analogue participants perceiving that the researchers were intending to "help" them and their community since the researchers appear to hold similar values. This is identification through, what I will term "we care" and "we will help." The invitation letter set the stage

[25] For a thorough examination of the evolution of Identification see: George, A., Selzer, J. (2007). *Kenneth Burke in the 1930.* Columbia, SC: University of South Carolina Press.

for this identification explaining that the trial "helps…families of young children develop positive parenting practices for healthy child growth and school readiness" (Appendix L). Burke observed, "A is not identical with his colleague, B. But insofar as their interests are joined, *A is identified with B. Or he may identify himself with B even when their interests are not joined, if he assumes that they are, or is persuaded to believe so* [emphasis added]" (1969, p. 20). The analogue participants were assuming the researchers shared their values, in part due to the inadvertent effect of the invitation letter. The *êthos* of the researchers, provided by their status, may also have contributed to identification in that analogue participants may have believed that persons in their positions would only do what is in the analogue participant's best interests.

Burke explained that Identification is necessary to overcome division. A clear source of division from the dominant culture, present for many members of this community, is an undocumented immigration status. This is a defining part of the identities of many community members. One way to examine this division is by employing another Burkeian concept, that of terministic screens. Burke (1996) observed, "Even if any given terminology is a reflection of reality, by its very nature as a terminology it must be a selection of reality; and to this extent it must function also as a deflection of reality" (p. 45). Terministic screens determine one's reality and "direct the attention" (p. 45). Burke (1996) explained,

> We *must* use terministic screens, since we can't say anything without the use of terms; whatever terms we use, they necessarily constitute a corresponding kind of screen; and any such screen necessarily directs the attention to one field rather than another. Within that field there can be different screens, each with its ways of directing the attention and shaping the range of observations implicit in the given terminology. All terminologies must implicitly or explicitly embody choices between the principle of continuity and the principle of discontinuity (p. 50).

When considering the social context of the participants of this study, the data suggests that they do see and conduct their life through the screen of their immigration status. A terministic screen includes considerations of the use of language and the words *undocumented* and *illegal* are laden with meaning. "Undocumented" conveys, according to Viera (2011), that the person has been "written out of one documentary society" (p. 457). Worse yet are the terms *illegal immigrant* or *illegal alien*. Garcia (2012) observed,

> When you label someone an "illegal alien" or "illegal immigrant" or just plain "illegal," you are effectively saying the individual, as opposed to the actions the person has taken, is unlawful. The terms imply the very existence of an unauthorized migrant in America is criminal (par 2, n.d.).

In fact, even the deportation process, the punishment for being in this country without following the proper immigration process, is a civil administrative procedure, not a criminal matter. This is a close knit community and those members that are documented are concerned for family and community members that are not. The lens of "illegal" that comes with a fear of deportation directs the way this community lives.

With respect to the results of this study, I have shown that the analogue participants hear the presented information through the screen of their social context. As was shown in the previous subsection, the ultimate motivation for this community, the telos of their migration, is "a better life." 'A better life' is the reason they are in this country and are confronting the consequences of being undocumented. The terministic screen of "a better life" directs attention to activities that work toward this goal while deflecting attention from the harsher realities of their lives. This may explain why the participants exhibited the therapeutic misconceptions they did by overestimating and misconstruing the benefits they would incur by participating in the public health trial.

Presenting information. As shown in the Results section, the participants of this study give many suggestions on how to improve the consent conference in order to

enhance understanding for members of their community. These suggestions are summarized below in Table 9. Advice on How to Improve the Consent Conference.

Table 9. Advice on How to Improve the Consent Conference

Communicate in a direct manner
Conduct the consent process with a group of Latinos rather than individually (Being in a group will provide participants confidence)
Confirm comprehension with exercises after each section of information
Focus on the main points
Have a face-to-face discussion (Allows for question and answer as well as stimulating interest and also prevents misunderstandings.)
Incorporate former or current Latino participants to provide testimonials
Keep presentation short
Present information in sections
Provide a strong introduction forecasting what will be covered (This will help keep people's attention)
Provide credibility by highlighting enroller's association with the University
Send all information via postal mail prior to the meeting (Knowing the topic in advance facilitates understanding)
Stress that enrollers are professionals
Use plain language
Use visuals in the explanations (To accommodate those with low literacy)

Many of these suggestions: keep the presentation short, provide a strong introduction, forecast what will be covered, communicate in a direct manner, use plain language, focus on the main points, and use visuals in the explanations are standard writing precepts, especially in professional writing. They work to produce a usable form

of communication. Several participants mentioned "plain language," however, it was unclear exactly what they meant by this term.

According to the government website, Plain Language.gov; Improving Communication from the Federal Government to the Public:

> Plain language (also called Plain English) is communication your audience can understand the first time they read or hear it. Language that is plain to one set of readers may not be plain to others. Written material is in plain language if your audience can:
>
> - Find what they need;
> - Understand what they find; and
> - Use what they find to meet their needs" (http://www.plainlanguage.gov/whatisPL/index.cfm)

This definition is useful in the context of this study only in that it suggests what a researcher might examine if looking for plain language in consent materials per U.S. standards. Plain language for this community would include considerations of education levels, literacy levels, familiarity with western medicine, familiarity with medical terminology, and familiarity with the concept of research.

Including visuals in the consent materials was suggested by several participants, with one saying,

> Because a lot of people are more visual. Some Latinos don't have an education so it's easier for them to learn and understand by seeing something… It's better…with images or pictures so they can hear and see.

In a previous research study I have conducted with individuals from a similar demographic, "Components of Effective Intercultural Healthcare Materials," I found a comparable preference for the inclusion of visuals,

> P: I think so too, that is good because besides the information they give you, they also give you some drawings and illustrations. You also learn from the illustrations.
>
> Facilitator: So you like them.
>
> P: Yeah, words with pictures or drawings work better to teach you.
>
> P: I like it when there are graphics so you can visualize it better ("Effective Intercultural Healthcare Materials," Pigozzi, unpublished manuscript).

Although there has been some research investigating the use of and the efficacy of visuals (including multimedia) for foreign-born Spanish speakers in the areas of health education and health communication (e.g., Leeman-Castillo, Beaty, Raghunath, Steiner, Bull, 2010) very little research has been done with this population with respect to the use of visuals in consent documents. One study by Clark, Mangram, Ernest, Legron, and Peratta (2011) showed the addition of a PowerPoint presentation did not increase understanding of risks and benefits of a laparoscopic cholecystectomy for foreign-born Spanish-speaking patients. One explanation for these results may be the lack of attention to other cultural values; the only variables attended to in this study were the inclusion of a PowerPoint and translation.

While some of the suggestions seem purely pragmatic, such as to communicate in a direct manner, focus on the main points, keep the presentation short, and make clear that the enrollers are professionals, they may also speak to issues of trust. Analogue participants in this study expressed a certain amount of wariness in participating in the NET-Works trial. One reason was that it involved their children of whom they are

naturally protective. Another is the possibility of exposure as an undocumented immigrant. Additionally, they may have felt that the enroller was not being totally honest with them. As a participant said, referring to community members,

> I think a lot of them are taken advantage of.

This participant then provided an example of what an enroller could say to reassure a potential participant,

> We're not going to get into your privacy, your relationships, instead of somebody as a gossiper; we are professionals in this thing.

Another participant speculated that Americans would not tolerate (or be given) a consent form any longer than three pages,

> It's [the consent form] a lot. Here no, Americans—three pages and that's it. Fast.

The advice that is specific to this Latino culture includes holding the consent process in a group, preparing potential participants by sending materials in the mail, advertising in a local paper, and having Latinos who have been or are currently enrolled in the study attend the consent conference to provide a testimonial.

I have discussed how Burke's concept of Identification was working in the simulation being presented in this study. I am unsure if the researchers of the NET-Works trial attempted to tailor their materials to better "identify" with Latino immigrants. Nevertheless, these potential participants did feel identification due to the fact that the public health trial dealt with topics that are deeply important to them: children, family, diet, and health. These are the cultural values that resonated.

In my previous research, mentioned above, "Components of Effective Intercultural Healthcare Materials," I showed that creating a means to identify with the person presenting the information is the reason one should reflect the ethnicity of the

audience in the message. The participants of this previous study did identify with the speaker as seen in these comments,

> P: I think that yes, it does make an impact whether the people speaking are Latino, because it's one thing when the do translations with someone of another race; here in the United States, they use different voices for the translations. Hearing our own voice has an added emotional value; you know everyone can get the same diseases, but seeing it presented by Latinos reassures us it's something that happens to us too.
>
> P: Or because seeing an American in the videos makes us worry to think that they can get the treatment for the ailments, but maybe as a Latino one cannot receive the same treatment. So there's that too.
>
> Facilitator: So that is important for you as well.
>
> P: Yes, because I think it is good to see it presented by other groups of people, but seeing a Latino reassures us that we as Latinos have the right to medical assistance ("Effective Intercultural Healthcare Materials," Pigozzi, unpublished manuscript).

The issue of racial concordance between the enroller and the potential participant is an important one. Except for one comment, racial concordance is not represented in my data. This may be because myself, the interpreter, and the enroller featured in the videos are all Latino and spoke in Spanish, therefore it was not an issue. Ford et al. (2013), in a study looking at unequal participation in clinical trials (with respect to African Americans and Latinos) found, "Latinos were much more likely to trust Spanish-speaking physicians and often complained that 'American' doctors did not have their best interests at heart and might be 'in it for the money'" (p. 34).

Promoting autonomy. I have argued that the autonomy of an individual is affected by their social context and have described the social context of this community as dynamic and complex. Among the challenges faced by community members are low

levels of formal education, low English language skills, much time spent working, resulting for some in poor nutrition, little physical activity, and inadequate supervision of children. An undocumented status affects all aspects of the community member's lives. In order to take into account the effects the social context have on an individual's autonomy, Sherwin (1998) introduces the concept of relational autonomy, which she defines as, "A relational conception of personhood that recognizes the importance of social forces in shaping each person's identity, development, and aspirations" (p. 35). Sherwin (1998) maintains a relational approach to autonomy "is able to provide us with insight into why it is that oppressed people often seem less autonomous than others even when offered a comparable range of choices. Under a relational view, autonomy is best understood to be a capacity or skill that is developed (and constrained) by social circumstance" (pp. 35–36).

Dodds (2000) adopts Meyers concept of autonomy competency in order to extend Sherwin's approach. In exercising one's autonomy, Meyers writes about the presentation and amount of information given in informed consent process saying the focus should be on "the development and exercise of people's autonomy competency" (as cited in Dodds, p. 231). Self-trust is another aspect of autonomy that must be considered. Finally, Gillies & Entwistle (2012) encourage researchers and those involved with trial enrollment to look closely at the consent materials, "Relational understandings highlight the potential value of some professional intervention as supportive of the development and exercise of autonomy by individual patients…encourage nuanced and context sensitive explorations of the appropriateness of various forms of communication" (p. 753).

These scholars are saying that researchers should be aware of and work toward the development of an individual's autonomy competency, including the element of self-trust. One way to practically consider how to work to develop an individual's autonomy competency in the informed consent conference is provided by Warren (1998). She distinguishes between what she terms as "housekeeping issues" (these are personal

issues) and "crises issues" (these are 'big' issues such as the withdrawal of life-support). What if, she asks, informed consent is viewed as a "housekeeping issue"? She illustrates this by asking the question, "How should we foster the conditions which make informed consent more likely?" (p. 79). This question urges reevaluating the relationship between researcher and potential subject. Warren then poses a potential solution to help overcome issues of power. She suggests that physicians (in this case we are thinking about researchers) consider themselves educators rather than authorities. "Teachers need to repeat, to connect with this student's experience, and to get feedback from students so that inaccuracies can be corrected. Teaching skills are hard-won—requiring practice, experimentation, and sensitivity to audience. The medical model downplays the difficulties of teaching well, tends to attribute failures of communication to patients" (Warren, 1998, p. 82).

When working with these community members in an informed consent conference, one shouldn't assume a lack of autonomy but should be aware of the real possibility of compromised or diminished autonomy due to their social context. Close attention to the social context (an audience analysis) can inform the approach to the consent conference. Researchers should consider themselves educators and approach the conference with a flexible attitude, being prepared to tailor the information to meet an individual needs and communication preferences. Researchers should attend to advice given by Paskett, Katz, DeGraffreid, and Tatum (2003) who remark, "The individuals delivering the information not only must demonstrate knowledge…but they also must express respect, compassion, sensitivity, warmth, empathy, honesty, flexibility, and support" (p. 610). Finally, listening to the potential participants is essential to effectively communicate. Simon & Kodish (2005), following Geerz, advise, "Rather than trying to learn about the multiple beliefs and customs of particular groups of people—an almost impossible task—we ought to listen and talk to people about their shared needs and preferences" (p. S134). Members of this community do feel that they are not heard,

> You, you should be very surprised how many people, how many people are out there that want to speak to someone and maybe not just for little one thing but on so many things but no one ever, ever bothers in ask them that and no one even bothers In knowing how to ask them.

Suggestions made by the participants in this study are useful to address the issue of diminished autonomy and are adaptable to Warren's (1998) education model:

1. Hold a recruitment conference for a group of Latinos rather than individually
2. Have a Latino who has or is participating in that or a similar trial available at the conference to answer questions and discuss their experience to increase an individual's capacity to trust their own decisions.
3. Have other family members and/or trusted community members involved in the conference.
4. Prepare potential participants by sending information my mail and publishing the upcoming trial within the community.
5. Shorten the consent conference and consent form.
   (A request for a shorter conference contrasts with requests for additional information on various aspects of the program, but the issue is the type of information being given. One solution to this discrepancy is to have multiple short meetings.)
6. Include visuals
7. Present the information in sections and confirm comprehension with exercises after each section. (This reflects Warren's suggestions.)

One way to shorten the conference is to provide less information to the potential participant. There is literature that supports providing less information during a conference. Dodds (2000) observes that providing large amounts of information does not protect autonomy. It may be better to provide counseling to assist the individual in determining "what it is he or she really wants in the context…[and] may better promote

autonomy than greater information" (p. 231). There is potential for an information burden; Epstein, Korones, and Quill (2011) observe, "cognitive overload from too much information may impair rather than facilitate understanding and decision making, especially when patients and families are under considerable emotional and physical duress" (p. 380).

Taking necessary time to conduct a conference is another consideration. Katz (1993) observes that in order follow his recommendations on how to best secure a morally valid consent (as compared to a legally adequate consent), takes time and "may have to extend over hours, perhaps even days, and must be continued until one is reasonably certain that the patient-subjects understand" (p. 36). This observation was also found in work done by Flory and Emanuel (2004) who showed more time spent with potential participants improved understanding. This investment in time would certainly improve the consent process for immigrant populations and would result in more equal sharing in power. Yet, research conducted by Edwards, Lilford, Thorton and Hewison (1998) found that more information and more time used in a consent conference resulted in lower enrollment rates. This may partially explain a reluctance by researchers to employ such an approach.

Conclusion. The telos of the communication process is to inform the potential participant in a manner that facilitates understanding and supports individual autonomy. The information is received through the social context of the potential participant lives. This social context has the potential to compromise the individual's autonomy. The communication of the information was discussed including practical elements for the consent process as well as cultural elements to connect, to promote identification with this population. The rhetorical concepts of identification and terministic screens provide useful insight into the prevalence of therapeutic misconception. Finally, approaching the consent process as an educator provides a way to effectively reach every individual, including individualizing the amount of information presented and the amount of time spent in the consent conference.

Inter-text

A conversation on healthcare

P1: Yes, because to us it is very difficult to get health insurance and then us, as a culture, we don't have the habit to check ourselves on a regular basis, only when we get sick do we go to the doctor and unfortunately once we get to the third age [old age] is when we get all these sickness together that could have been prevented but we don't have the same health habits compared to other cultures.

P2: The doctors said, it is just a matter of time and the other thing is we don't have health insurance. We are going to discount places until we get the insurance, which is time consuming going around and we just let it go. I feel fine even with high blood pressure and its best I drink a tea to control anxiety and keep going. But the people who are born in this country have been educated and have one to two doctors' visit per year including dentist but not us because of the insurance and it is too expensive.

P3: I have a friend who has diabetes and I asked her if she has the device to measure her blood level and she said they only detected it, but since she does not have insurance there is nothing she can do.

P4: I don't know much about diabetes besides there are Type 1 and Type 2. I'm learning through my dad, looking at what age we are more susceptible to sickness and many of us don't even know.

Chapter 4 Study 2

In order to ensure the categories in this project were developed as thoroughly as possible, I saturated the categories with additional data looking to see if new properties emerged. This was done by theoretical sampling, "seeking and collecting pertinent data to elaborate and refine categories in your emerging theory" (Charmaz, 2006, p. 97). The data in Study 2 was collected at a second urban Catholic church that serves a large Latino population.

Methods

No hay curva mala pasándola despacio
There is no bad curve, passing it slowly

In this section I describe methods that differed from those detailed in Chapter 3: Study 1 and do not go into detail on those matters that remained the same in this research phase except when needed for clarity. In order to continue data collection I submitted an IRB "Change in Protocol" form and received approval on March 7, 2014. The requested and approved changes were to do the following:

- Increase the number of participants from 20 to 200 (this was at the suggestion of IRB who felt I should apply for a large number to avoid having to continue to submit Change of Protocol requests).
- Increase the number of research sites from one to four.
- Increase the monetary amount of the gift cards given to the participants from $10 to $15.

Location. I chose a second urban Catholic church that serves a large Latino population to recruit participants. This church was chosen for the same reasons as the church chosen for Study 1) it provided access to a convenience sample of participants; 2) it provided the participants, the majority undocumented immigrants, a place that felt safe and familiar; 3) it provided a location that was assessable to the participants using available transportation; and 4) previous research I had conducted with this same population, "Effective Intercultural Healthcare Materials" (Pigozzi, unpublished manuscript), confirmed that the participants felt comfortable holding conversations in the churches and that providing food (meals or snacks) and activities or a caregiver for accompanying children was culturally appropriate and appreciated.

I began recruitment in the same manner as Study 1, by obtaining permission to recruit participants by sending an email to the parish priest in which I introduced myself and my research plan. The first email was sent March 12, 2014. In this phase of the research I used focus groups mainly for logistical reasons. The focus groups were held after the 11:30 am and 6:00 pm masses on June 8, 2014, and June 22, 2014. This priest was especially interested in the topic and returned my initial email with this note,

> Hola Laura,
>
> As a former mental health practitioner, I am extremely interested in this issue. I have wondered about that since my start here as a pastor five years ago. How is informed consent understood, if at all, by immigrant Latinos, and what are the ethics of garnering a signature when the consequences are not understood.
>
> You are welcome to conduct interviews at (name removed)! I'd be happy to get together with you to discuss this in more detail. I may invite others of our staff to be present if possible, too.
>
> Thank you for this overdue research! (personal communication, March 13, 2014).

I subsequently had a face-to-face meeting with this priest introducing him to the details of the project. He also introduced me to a member of the parish staff, a woman who provided mental health services to the community, among other duties. She was very helpful in assisting in recruiting participants as well as providing insight into the community.

Further email exchanges dealt with the logistical issues including the recruitment flyer (Appendix S) and the location within the church for the focus groups. On the days the focus groups were held the interpreter made an announcement at the end of mass inviting people to the lower level of the church to take part in the research while sharing a meal.

Research design and methods. Study 2 utilized the same videos and textual artifacts that were used for Study 1 as the stimulus (see p. 78 in Chapter 3 for a complete description of these materials as well as the justification for their use). The focus groups took place in the lower level of the church (see Figure 6.).

In Figure 5. you can see the video being projected onto a screen. The participants viewed the videos from the chairs and then moved to the tables for the discussion (Figure 6.).

Figure 5. Focus group video viewing and discussion space

Figure 6. Focus group discussion space

Figure 7. Transporting the meal

Figure 8. Meal for the participants

At the start of the focus group, I invited everyone to help themselves to the meal. The children took their plates and went with two women from the parish to an adjoining room. The analogue participants were asked to be seated around the table. I then thanked the participant(s) for coming and explained the intent of the study. The analogue participants were given this study's informed consent form (Appendix G). If requested or if we sensed it necessary, I or the interpreter read the consent form aloud in Spanish to aid those with low literacy. At this time any questions or concerns were addressed, and the analogue participants were asked if they would like to continue with the study. Though mention of audio taping the interviews had been made in the consent form, I reiterated that procedure and asked if the analogue participant was comfortable with the taping. I explained that I wanted to hear everything they had to say and it would be difficult for me to remember our conversation without the tape. Signatures were not required on the consent form (via permission from IRB), although I offered each participant a copy to keep for their records. I then administered a short demographic questionnaire (Appendix H), reading it aloud for any individual I felt was struggling with literacy. The "Short Assessment of Health Literacy for Spanish Adults" (SAHLSA-50) questionnaire, which assesses a Spanish-speaker's ability to read and comprehend medical terms (Lee, Bender, Ruiz, & Cho, 2006) (Appendix I) was read to the entire group. This represents an adaptation of the original intent of the tool, which is to also assess reading ability and traditional literacy.

Prior to viewing the videos (Appendix J & K), I briefly defined the concept of clinical trials and explained the concept of being an analogue participant specifically that they were pretending to be in this situation. The analogue participants were next given the NET-Works study invitation letter to read or have it read to them (Appendix L). They were instructed to pretend that this letter had arrived in the mail at their home and a week or two after their receipt of the letter the enroller in the video has come to their home. To simulate this visit, the analogue participants were asked to be seated in the chairs facing the screen and were shown the priming video which provides the background necessary for the analogue participant to understand why the analogue

participant's physician has suggested they consider participating in this public health trial. At this time the analogue participants were given the NET-Works informed consent form and were asked to consult it while viewing the conference video (Appendix M).

A focus group (Marshall & Rossman, 2011; Krueger & Casey, 2009) which was audio recorded, followed the viewing of the videos using a semi-structured interview format (original interview questions can be found in Appendix N). At the end of each focus group the participants were thanked and given a $15 Cub Food gift certificate. A total of 35 people participated in the four focus groups.

Data analysis. All audio recordings were transcribed and then translated into English. Possible limitations and complications that might arise from translating from one language into another will be addressed in Chapter 7: Implications, Research Quality, Limitations, Future Research. This phase of data gathering employed theoretical sampling, which is used to refine the theoretical categories by elaborating their properties. Glaser and Strauss (1967) define theoretical sampling as "the process of data collection for generating theory where by the analyst jointly collects, codes, and analyzes his data and decides what data to collect next and where to find them, in order to develop his theory as it emerges. This process of data collection is controlled by the emerging theory" (p 45). There is some variation of the definition of theoretical sampling among contemporary researchers who use grounded theory. For example, Charmaz (2006) believes categories need to be identified before using theoretical sampling, "Because you intend to use it to elaborate and refine your theoretical categories, conducting theoretical sampling depends on having already identified a category(ies)" (p. 103). I am most closely following the Glaser and Strauss (1967) conception of theoretical sampling and the Charmaz (2006) approach.

I first coded the transcripts using the initial codes from Study 1 when applicable. When new codes were needed I examined the existing categories for applicability. Through memo writing I was able to elaborate the properties of several categories in

meaningful ways. The data from this phase of research is reported in the next section, Chapter 4 Results.

Results

En boca cerrada no entran moscas

Flies do not enter a closed mouth

Demographic data and SAHLSA-50 Results (n=35).

Table 10. English Fluency Study 2

	English Fluency* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 2	11%	7–>12	40	1–36	12

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

Table 11. No English Language Skills Study 2

	No English Language Skills* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 2	53%	0–>12	50	<1–41	10

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

As in Study 1, all analogue participants completed the Demographic Data Form (see Appendix H) and the Short Assessment of Health Literacy for Spanish Adults (SAHLSA-50) (see Appendix I). A complete listing of the raw data can be found in Appendix O. The number of analogue participants in this research study was 35, however only 32 demographic forms were gathered; no doubt a result of latecomers who did not fill out a form. Also, eight SAHLSA-50 forms were separated from their corresponding demographic forms.

Of the 32 individuals who filled out demographic forms, only six (19%) reported speaking English fluently (with a score of 4 or 5, with 5 signifying fluent English language skills). Two of these individuals were born in the U.S. and as such will not be considered. Of the remaining four individuals, all had all received education, one person reporting seven–nine years of education, two reporting 10–12 years of education, and one reporting more than 12 years of education. There were no other correlations within this group. They ranged in age from the 18–25 year range up through greater than 65 years of age. The years in the U.S. range from the one–three year range to 36 years. One individual received a SAHLSA-50 score of 37 indicating inadequate health literacy. Two other analogue participants scored relatively high, with scores of 43 and 48. The third did not have a SAHLSA-50 form associated with his demographic form.

Seventeen analogue participants (53%) reported very little to no English language proficiency. Seven of these individuals reported a low education level from zero to six years, five reported an education level of seven–nine years, three reported an education level of 10–12 years, and two individuals reported an education level of greater than 12 years. One of these individuals scored a 48 on the SAHLSA-50 and the other scored a 45. One outlier in the SAHLSA-50 scores was a 46 score by an individual with an

education level of 1–6 years. The remaining SAHLSA-50 scores were low, indicating poor to inadequate health literacy. There was no correlation with the number of years in the U.S. with any of the other variables; time in the U.S. ranged from less than one year to 41 years.

Finally, nine analogue participants (28%) reported a moderate level of English language proficiency, indicating a level of 3 on the scale of 1–5 with 5 representing English fluency. Interestingly, all but one individual reported either an education level of 10–12 years or greater than 12 years. With the exception of two individuals, all SAHLSA-50 scores were low. There was no correlation with the number of years in the U.S. with any of the other variables; time in the U.S. ranged from 5–10 years to 30 years.

The same NET-Works materials that were examined in Study 1 were used in Study 2 of the study.

Categories. This phase was a form of purposeful sampling known as theoretical sampling. After coding and examining the Study 2 data, I found no negative cases to the initial nine categories. These categories are: Immigration Status, Effects of Working, Community's Diet/ Nutrition and Health, Education, Issues of Power and Trust, Understanding, Not Understanding, Therapeutic Misconception, and Presenting Information. However, the data provided elaboration on the properties of these categories, with some categories significantly refined.

Immigration status. Study 1 category definition: The category Immigration Status includes data related to the analogue participant's status as documented or undocumented immigrants. Though many participants were likely documented, they most likely had family or friends in the community that were not. Therefore, this is an overriding issue that affected the entire Latino community.

Data from Study 1 showed that being undocumented is an overriding issue for many who are continually fearful of being deported. This was seen to be a factor

restricting participation in a study or trial. The concern over an undocumented status was also evident in this data. Some analogue participants heard that that the study was connected with the federal government. I'm not sure what part of the consent conference they were hearing this, perhaps in the description of the mandated reporter status of the researcher. Unlike Study 1, some analogue participants asked directly about immigration status,

> Is this for illegal or legal people?
>
> Is there any problem facing deportation? People don't want to participate because of that.

There were also concerns, similar to the analogue participants from Study 1, about what exactly a mandated reporter could report,

> I'm worried because if the children accidently fall and get a blow and later one has a problem because children are naughty or the parents are spanking them due to misbehavior and they tell people other things, then we have a problem.
>
> Explain this to us because if we have a family benefit and then you bring me to the police, why?

This data strengthened and confirmed the properties of documentation status being an overriding issue and the mandated reporter status being a restricting factor to trial participation. Within the property of the mandated reporter are issues of deportation, including the separation of families, as well as confusions over what classifies as violence and abuse.

In addition to elaboration of this category's identified properties, an important issue emerged; that of health being a right of the undocumented. In this section, I provide a sample of such comments, with an analysis provided in Chapter 4 Discussion,

> Health has nothing to do with immigrant status.
>
> Each of us need to have health, I feel it's our right.

Effects of working. Study 1 category definition: The category Effects of Working includes data describing how work is viewed and how it affects members of this community. The data shows that the analogue participants work many jobs and this affects the family's diet, physical activity, the care of the children, and may restrict participation in trials due to time restrictions.

This data strengthened and confirmed the properties of the category Effects of Working, for example how work affects the family's diet,

> We don't have time to cook healthy once we come home from work and we just cook anything that is not healthy for our kids.

As in Study 1, Study 2 analogue participants also discussed how time spent working prevented parents from encouraging their children to be physically active. In fact, in this example, the grandparent termed this "abuse,"

> To me abuse is when the parents don't pay attention to their children, the don't take them to do activities or encourage them to do better in life—she [daughter] has to work a lot; therefore she doesn't pay attention to the kids to raise them with family values.

Finally, this data also described how working many hours results in a lack of attention paid to the children, which in turn affected their behavior,

> I think José's [the enroller in the video] goal is for parents and kids to get family counseling; family programs because many times as parents we believe we are right and trust our kids to communicate but it doesn't happen because when we have one or two jobs we just can't pay attention to them. That's why kids become rebellious.

This is an interesting comment in that there was no mention of family counseling in the simulated conference, only in the focus group discussion. This is an example of therapeutic misconception. The data from Study 2 did not result in any additional properties within this category.

Community's diet/nutrition and health. Study 1 category definition: The category Community's Diet/Nutrition and Health is closely linked with the category Effects of Working in that lack of time was considered by many analogue participants as the major factor in the poor diets of many in the community. This category, Community's Diet/Nutrition and Health, categorizes data concerning the community's dietary habits and health concerns.

The Study 2 analogue participants voiced concerns similar to those in Study 1 regarding a lack of time (due to work schedules) to prepare healthy food for the family. Also similar was the desire to learn about a healthy diet,

> The parents work all day and even so, we are willing to get involved and even attend school to get educated in this subject [a healthy diet] taking a half an hour to get this accomplished.

The lack of time is reflected in this comment in that the analogue participant stipulates the amount of time she is willing to give to a class on the subject of a healthy diet, a half an hour. Another analogue participant pointed out that not everyone is willing to change their diet,

> It depends on each person, some of them are very flexible to receive information but some others are very negative saying it's not convenient. Look, there are many people that if we start talking about changing their eating habits they will tell you they are living just fine and try to compare with you by saying, you are fat, I'm skinny.

Unlike the comments in Study 1, where analogue participants described their children's school lunches as healthy, one Study 2 participant correlated poor school lunches with childhood obesity, stating her children's school serves unhealthy food and offers no opportunities for exercise or sports. Lack of activity, which was a prevalent topic in Study 1 data, is also evident in this comment. Parents' work schedules were the reason given for the parent's inability to encourage their children to carry out physical activities.

The discussion about health in Study 2 was much more robust than that in Study 1. The conversation provided in the inter-text preceding this chapter (see p. 170) shows how some members of this community manage their healthcare. The analogue participants explain that they do not get regular medical or dental check-ups, like Americans, due to lack of health insurance and monetary resources, so they wait until they are sick to see medical care. In old age they come down with maladies that could have been prevented. One analogue participant stated that he felt fine even though he has high blood pressure. He also mentioned he drinks a tea to help with his anxiety and he just "keep[s] going." Another analogue participant in this conversation spoke about her diabetic friend who, since she had no insurance she could not get a glucose meter to measure her blood sugar.

During a focus group discussion of the simulated conference, analogue participants asked if the NET-works study provided medical care,

> Do you offer medical services here?
>
> We need somebody to provide medical assistance to keep track of our health.

One analogue participant spoke about the availability of ObamaCare for immigrants who are in this country legally,

> Obama made many changes, such as people who are legal no longer have a medical card that charges them the full fee.

An additional property, or perhaps an additional category, emerged. This topic is the importance of the community to its members and the care and concern exhibited for one another. The data within this topic reflects the analogue participant's concept of community and how it functions. The pronoun "we" is used throughout all focus groups' conversations and it is consistently used in these comments, for example,

> We want an explanation for our community so everybody can have an opinion on this topic.

> Can we involve more people in this program?

Being well educated on their children's health, participants felt, helps the entire community. Some analogue participants were concerned about the community members that would not be eligible for the NET-Works study,

> You explained it's all about the children and what about seniors? They are left behind? What about all the family?

The implications of this data on the provisional theory will be explored in Chapter 4 Discussion.

Education. Study 1 category definition: The category Education includes data related to issues affected by an individual's educational level. These issues are varied; and are interrelated to items within other categories.

This data strengthened and confirmed the properties of the category Education, for example requesting education on healthy foods. Also indicated, similar to data from Study 1, is the effect of a low level of formal education on understanding the study information and on agreeing to participate in the study,

> You need to explain to us because we don't have the education or knowledge of what we are going to sign.

The data from Study 2 did not result in any additional properties within this category nor was the category represented as strongly as it was in the Study 1 data.

Issues of power and trust. Study 1 category definition: The category Issues of Power and Trust includes data involved with concerns about confidentiality and issues of power and trust that were sparked by the consent conference.

Study 2 data was stronger than Study 1 date within this category. There was emphatic questioning on the purpose of the NET-Works study, the focus of the study, and the possible risks,

> The community can say it's OK to and could be good for our finances, but we want more information on exactly how this works and the consequences if any.

Another concern was what seemed to some as an unwelcome focus on the Latino community,

> Why are you now considering Latinos to participate?

> I want to know why only Latinos? Are there more communities involved or just Latinos?

As in Study 1, involvement of the government was viewed warily:

> The video shows attorneys saying we have the support of the federal government, but if we want this program for the immigrant Latino communities, how does this affect the federal government?

Distrust and caution was also evidenced in the desire to speak face-to-face with the researcher. Contacting a person by phone is insufficient because,

> We don't even know who we are talking to.

There was also distrust with information posted on a website,

> I think sometimes it [information on a website] is not the right information to be safe. We can't take the risk just like that.

This communication preference will be explored further in Chapter 4 Discussion.

Understanding. Study 1 category definition: The category Understanding includes data that demonstrates an understanding of specific information presented during the simulated study consent conference.

The initial codes that are included in this category represent the analogue participant's assertions of understanding, which may or may not represent a correct understanding. The use of the pronouns "we" and "us" along with references to the community demonstrate that the information is being understood through the lens of community. This tendency is much stronger in this study.

Analogue participants felt they understood one or more of the following points: that home visits would happen, the trial details generally, and the risks of the trial. Only two of the analogue participants understood the concept of groups (randomization).

Unlike Study 1, where no participants seemed to understand why the trial researchers wanted a hair sample from the children, two analogue participants understood that the hair is needed to check for stress levels in the children. This information was not conveyed in the video, but it was included in the consent form. On the topic of taking the hair sample one participant commented,

> I won't take any risk cutting my girl's hair if you don't explain to me the secondary effects, risks, so I can get educated by asking the consequences because I had an experience once when I was pregnant; they gave a medicine that causes rash to my baby and I didn't know what

> the medicine was. It's important to ask and don't be afraid because it is our lives and our children.

This was an example of contextualizing to form, meaning using a familiar experience to make sense of a new experience. There were two more examples of this technique shown in the data,

> His [José, the enroller in the video] idea is to be alert in our families and with our kids if there is any risk they may have…In my case, but I didn't ask the doctor, I had been having problems with my skin and being shy can cause side effects in the long run.

> I don't feel people agree when we talk about investigations, they have to make sure it is something that won't affect them. I remember long ago my son [who is affiliated with the University] spoke to me about the University looking for families who would agree to have their children participate in this study regarding brain behavior and been told, this is not X-rays at all, it won't affect them, but there were two or three people who disagreed, especially when there is no guarantee.

The intercultural communication implications of this technique, contextualizing, will be explored in the Chapter 4 Discussion.

Therapeutic misconception. Study 1 definition: The category Therapeutic misconception includes data that demonstrates what occurs when research participants believe or assume that their trial participation will provide them with the greatest possible therapeutic benefits, meeting their individual needs.

Therapeutic misconception was apparent in the data, though one topic was very different from those heard in Study 1, child sexual abuse. This comment was offered in response to the question, Do you understand the goals of this study?

> Educate the children more in a way so that they can't be abused by anybody, something better for our kids future; not sexual abuse. These are the things that are very important because we are many families in this country affected that way and they don't report to the police. Certainly, in those cases we need someone to guide us because there are things we don't know. There are things that happen in school and we don't even know. Our children are afraid to let us know, they don't know how to explain because mom or dad get upset and many times we face situations like that, therefore, we need to know how to ask our children so they can trust us.

After this statement, another person referenced the mandated reporter status of the researchers saying it is good because they check for abuse so they can report to the police. Parents also have difficulty discussing sexual matters with their children,

> Speaking about sexuality we are very closed minded and we don't want to speak about this topic which is very important so our girls won't become pregnant or our boys get any sexual transmitted disease. It's very important to take family classes to learn how we can help our family.

A different analogue participant felt the NET-Works program should provide family counseling; this concern mirrors comments from Study 1 about children being less respectful to their parents,

> Our kids became more rebellious also. We can't even say anything to them because they confront us as parents plus they are going to school and they changed. They are more disrespectful and confront parents face to face. The schools need to set more discipline because our kids need better behavior and respect their parents. We need family counseling, a psychologist therapist.

A response to this comment was a therapeutic misconception of the NET-Works trial with respect to this specific concern,

> I think José's goal is for parents and kids to get family counseling; family programs because many times as parents we believe we are right and trust our children to communicate with us but in reality it doesn't happen because when we have one or two jobs we just can't pay attention to them.

These therapeutic misconceptions will be examined in relation to those that emerged in Study 1 in Chapter 4 Discussion.

Not understanding/misunderstanding. Study 1 category definition: The category Not Understanding/Misunderstanding includes data that demonstrates an analogue participant is not understanding or misunderstanding the study consent information.

The initial codes that are included in this category represent analogue participant's direct statements of not understanding something or represent a clear example of misunderstanding a point of the presented information. The topics of misunderstandings included some specifics similar to the misunderstandings shown in Study 1 such as various study details and randomization.

There were instances of individuals not understanding the purpose of the study nor what it entailed,

> I didn't understand. How does it start and how does it finish?

> It is clear but I think you can explain a little bit more.

Unlike Study 1, where most understood the voluntary nature of the study, at least one analogue participant remarked,

> Once you sign, you can't have regrets.

Similar to Study 1 there were misunderstandings surrounding randomization and the fact that the trial had two arms. There were also misunderstandings about the risks of participation, which were not seen in Study 1. One analogue participant thought there

was a risk if the child is overweight and they jump or run. This participant went on to say that if that were the case, the child would walk instead and that is the education they would receive. Another analogue participant thought there was risk of not being able to do exercise during the three-year period of the study. One analogue participant felt there was a possibility that their children would be given medicine,

> They don't talk about medicine and I'm afraid for my children to take part in the study. I won't agree with that.

A participant thanked me for providing school meals,

> I don't have time to prepare healthy food and it seems to me that you are willing to provide these meals to kids through the schools. Thank you.

Finally, an analogue participant thought there was support from the federal government for the study but it is was not clear to them if there was support for the community. They asked, if the community are the ones to take the risks, what are their benefits?

This data will be examined against the Study 1 data in this category.

Presenting information. Study e 1 category definition: The category Presenting Information includes data concerned with the process of communicating study information during the informed consent conference.

The initial codes included here are comments asking for additional information on a variety of topics, comments regarding education levels, and many pragmatic suggestions by the analogue participants on how best to convey the information for this study.

Two analogue participants requested that the information clearly state whether or not "illegal" people can participate. This had not been verbalized in Study 1. Others wanted to know what would be talked about in the home visits. Most of the requests for

more information were wanting detailed clarifications, for example, not only what the belt is and does, but what it is not (it does not use X-rays). Promoting the program in church was important to one analogue participant,

> So people can feel more secure.

Similar to advice from Study 1 a participant advised staying with two or three clear points and don't elaborate too much.

Several analogue participants said the consent form was "too long." One analogue participant stated,

> I don't think it's well explained in the video.

Two statements made a distinction between receiving information and understanding the information,

> They told us but they didn't explain.

> You gave me the information but you didn't explain it to me.

In order to better understand the conference information several participants recommended that the information be explained verbally, step-by-step. This would especially aid those with little education. One analogue participant blamed laziness for wanting a verbal explanation,

> That's what we need because Latino communities are lazy to read and we want them to tell us, here you can have a problem or here not.

Participants also had suggestions for changes in other aspects of the conference. There were several comments reflecting a desire to bring the materials home to think things over, with subsequent meetings to discuss the trial. One way to do this, a participant suggested, was to have a researcher present information during a family meeting at the family home, then return a few days later with more information. An

important part of the process, analogue participants explained, was the opportunity to ask questions,

> It's very important to ask questions, specifically can you tell me what the purpose of this study, side effects, consequences, what are the benefits or disadvantage in the future?

The importance of asking questions as part of the process of receiving information was expressed more robustly in this data than in Study 1.

Another aspect of the conference that could be changed, in the opinions of the analogue participants, was the addition of a persuasive element, which participants referred to as "motivation." saying if they don't have motivation they won't participate,

> Get me motivated and clarify what you want us to do.

Or this was referred to as being "convinced,"

> Convince me and show me this program it for good and I will be happy to sign up for the programs you believe are good for the kids.

Two final, unrelated points were a suggestion that the word "study" be used instead of "investigation" because the term "investigation" sounds like a police term and an example of absence of attention during the conference,

> Our minds are away from the meeting and we didn't pay attention to be honest.

Table 12. Advice on How to Improve the Consent Conference—Study 2, shows the advice on how to improve the consent conference from the analogue participants of Study 2. While Study 1 data provided general pragmatic suggestions as well as culturally specific suggestions, Study 2 suggestions are all specific to this culture.

Table 12. Advice on How to Improve the Consent Conference—Study 2

Clearly state whether "illegal" persons can participate
Extend the conference into several meetings, possible conducting these in the potential participant's home.
Motivate the potential participants
Promote the trial in the church
Read all materials aloud
Use the term "study", not "investigation"

Analogue participants in actual NET-Works study. As in Study 1, two of the analogue participants were actual participants in the NET-Works study. One analogue participant talked about speaking with someone about the program. She spoke knowledgably about the study. I don't know who she spoke with so perhaps she spoke with someone who is actually in the program or else someone who had been in a focus group from the week before.

In the final focus group of this research study there was a man who had been participating in the actual NET-Works study for the past two years,

> I like to participate in this beneficial study not only for us but for all Latino community, I think is the most important.

When talking about the hair sample this participant said,

> Little girls have long hair but boys are more noticeable when they make a hole and people start asking what happened? Is he sick? The first time they made a big hole and took a little time to heal, especially when he made a hair style and people saw him thinking he was sick and I told them he was in a research study.

It is possible that this participant was illiterate. The following comment suggests he did not have the ability to write down the required information,

> It takes a little bit of time to memorize the meals from the day before, portions, what we consumed.

The conceptual framework reflecting this new data is provided on the next page. The following section, Discussion, explains this evolution of the theory as illustrated in the conceptual framework.

Conceptual Framework Study 2

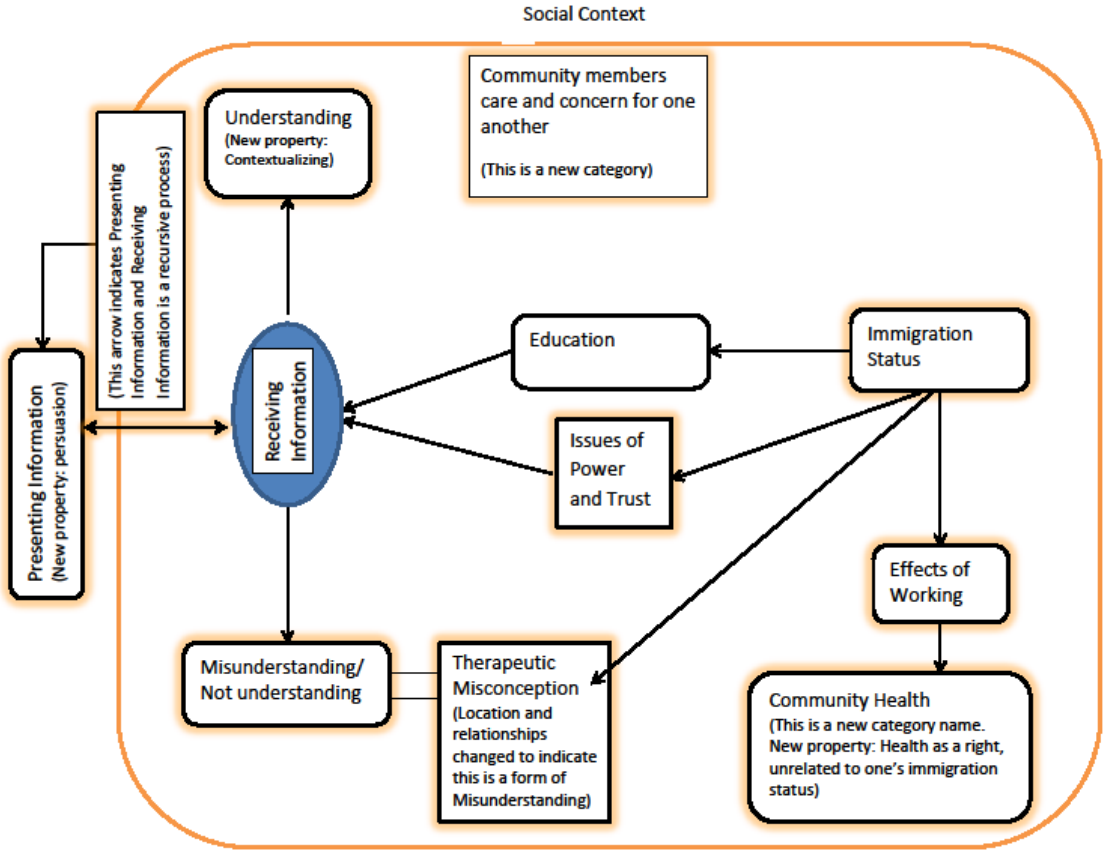

Figure 9. Conceptual framework—Study 2

Discussion

El que quita la ocasión, evita el ladrón

Who takes away the opportunity, avoids the robber

When the data from Study 2 is considered, the answers to the research questions and the provisional grounded theory are refined.

R1: What do Latino immigrants understand from the informed consent process?

The participants in this study understood they were being invited to take part in a study that involves their children. What was understood varied among participants. Least understood was the concept of randomization. Therapeutic misconception was evident; participants perceived personal benefits that were greater than the actual possible benefits or were specific to their individual needs.

R2: Is there information important to the participants that is not being communicated?

Participants requested further information on study details involving visits to their home and further qualification on the mandated reporter status of the researcher. They requested assurances of confidentiality and clarity on the risks involved.

R3: How adequate is the structure of the conference?

This question is best answered by Table 12., the suggestions given by the participants on how to best present this information to Latinos. Many suggestions were pragmatic and reflected some

standard usability guidelines: keep the presentation short, provide a strong introduction forecasting what will be covered, communicate in a direct manner, use plain language, focus on the main points, and use visuals in the explanations. Some advice was specific to this culture: clearly state whether or not undocumented persons can participate, hold the consent conference in a group, extend the conference into several meetings, read all materials aloud, prepare potential participants by sending materials in the mail, advertise in a local community paper, promote the trial in the church, have Latinos who have been or are currently enrolled in the study attend the consent conference to provide a testimonial, and motivate the potential participants.

R4: What facilitates participation for this population?

Community members were interested in participating in studies that address issues that are relevant to them or their community. They look at how they or their family might benefit from participation; at times overestimating the benefits they might receive (therapeutic misconception). Monetary compensation was important for some, an educational component was important to most. That the trial benefits as many community members as possible was an important consideration.

R5: What restricts participation for this population?

Anything that may expose a participant as undocumented restricts participation, such as the mandated reporter status of the researcher. This included a general distrust of the enroller or the study. Research involving family was often approached cautiously. Another deterrent for this community was a lack of

> time due to work responsibilities. Finally, lack of education can interfere with understanding. If it was not clear to the participant what the study was about they would not agree to participate "because if I don't understand I won't sign."

This section explicates the revised provisional grounded theory by describing what was found in the Study 2 data and how that data strengthened and confirmed the existing categories. Refer to Fig. 9 at the beginning of this section to view the modified conceptual framework which visually displays the modified provisional grounded theory. The colored outlines around a category indicate that the properties of that category were elaborated in this research phase, at times changing the category's name. The category "Community members care and concern for one another" is new and will be explained below.

Historical context. The Study 2 research was conducted in June 2014. For a brief glimpse of the political climate, I include the results of a national survey conducted by The Pew Research Center during the period of February 14–23, 2014 involving 1,821 adults. The results showed that 73% of the participants felt that people who are in the United States illegally should be allowed to remain in this country if they meet certain requirements. However, though there was support for granting these immigrants legal status, 46% felt that they should not be allowed to file for citizenship. Fig. 10 details the survey results ("Public divided over increased deportation of unauthorized immigrants," 2014).

Majorities of Republicans and Democrats Favor Path to Legal Status for Undocumented Immigrants

	Should be allowed to stay legally	And be able to apply for... Citizenship	Permanent residency	Should not be allowed to stay legally	DK
	%	%	%	%	%
Total	73	46	24	24	3=100
White	70	43	23	28	2=100
Black	77	57	16	21	2=100
Hispanic	89	57	30	8	3=100
Republican	64	32	29	34	2=100
Cons Rep	61	31	27	37	2=100
Mod/Lib Rep	72	34	32	28	1=100
Independent	74	47	25	24	3=100
Democrat	81	56	21	17	2=100
Cons/Mod Dem	73	46	22	26	1=100
Liberal Dem	90	66	20	8	1=100
Among Rep/Rep lean					
Tea Party	56	25	28	41	3=100
Non-Tea Party	69	40	26	29	2=100

Survey conducted Feb. 14-23, 2014. Whites and blacks include only those who are not Hispanic; Hispanics are of any race. "Don't know" responses to question about citizenship/permanent residency are not shown. Figures may not add to 100% because of rounding. Q24/Q25.

PEW RESEARCH CENTER

Figure 10. National survey on legal status for undocumented immigrants

Social context. The following discussion describes how Study 2 data impacted the composition of the Social Context. In some cases, it strengthened and confirmed the identified properties of a category, in other cases new properties were identified. One new category was also identified.

As previously explained an undocumented status touches all aspects of an individual's life and influences what jobs are available and often limits education opportunities. An undocumented status often causes individuals to approach situations

warily, including trial participation. Lack of English language proficiency also limits employment opportunities and contributes to community isolation. The data from this research phase strengthened and confirmed these properties of the category of Immigration Status. An additional property emerged, that of health being everyone's right and it should not be tied to one's immigration status,

> Each of us needs to have health; I feel it's our right.

However, the category Community's Diet/Nutrition & Health illustrates how factors directly related to being undocumented affects the health of community members. This additional property, health being everyone's right, strengthens the connections between these categories. The category will now be named Community Health, with community diet/nutrition becoming a property of this category.

A central reason for the poor diet of community members is time spent working. In the category of Effects of Working, analogue participants have described the difficulties of balancing work responsibilities and caring for their families. With both parents working multiple jobs, there was little time available for them to help their children with their homework, encourage and facilitate physical activities, supervise the children, and maintain a healthy diet. The data from Study 2 strengthened and confirmed the properties of the category, for example,

> We don't have time to cook healthy once we come home from work and
> we just cook anything that is not healthy for our kids.

An analogue participant, a grandmother, termed lack of attention to children as "abuse,"

> To me abuse is when the parents don't pay attention to their children,
> they don't take them to do activities or encourage them to do better in life.

As significant as the effects parents' lack of time have on diet, physical activity, and child supervision is the effect on the traditional family structure. As was noted in

Study 1, within the traditional cultural construct of *familismo*, traditional families live in a patriarchal arrangement and follow traditional gender roles. In the immigrant families in this study both parents often work, causing a disruption in a traditional family structure without, perhaps, a clear way to negotiate this new reality. The children often preferred to spend time with friends rather than the family and were, at times, disrespectful to their parents. This was confirmed and stressed in Study 2 with observations such as this,

> On the other hand, our kids became more rebellious also. We can't even say anything to them because they confront us as parents plus they are going to school and change. They are more disrespectful and confront parents face-to-face. The schools need to set more discipline because our kids need better behavior and respect their parents. We need family counseling, a psychologist therapist.

The discussion on the community's health was much more robust in Study 2 than in Study 1, another reason to elevate the code Community's Diet/Nutrition & Health to Community's Health. The analogue participants explained that that many community members do not have insurance or monetary resources and as a result do not get regular medical check-ups and do not seek medical care unless they are ill. In old age they present maladies that could have been avoided had they received preventative care. One analogue participant shared that he drank tea to help with his anxiety. This was the first mention of the use of natural remedies, though it was not clear if this was a traditional remedy (folk medicine). Another participant discussed her understanding of ObamaCare and reminded the group that it is available for those with papers. This is illustrative of the previously mentioned statements that health is a right and should not be contingent on immigration status.

A new category emerged in Study 2, that of Community Members Care and Concern for One Another. This category represents the importance of the community to its members. The pronouns "we" and "us" were used extensively as well as comments directly reflecting care for community, for example,

> We want an explanation for our community so everybody can have an opinion on this topic.

After noting this pronoun use, I reviewed Study 1 data and found that "we" was used to some extent, though not nearly as widely. However, concern of community members was evident, confirming this category. This category also strengthens the suggestion to conduct trial recruitment with groups of Latinos rather than individually.

As visually represented in the conceptual framework, the category Education includes data related to issues affected by an individual's educational level. These issues are varied and are interrelated to items within other categories. The data from Study 2 confirmed the properties of this category and reinforced the negative effect of low formal education levels on understanding trial information. This in turn points to the importance of how trial information is presented, which will be discussed further when examining the category of Presenting Information.

Fear of deportation is at the root of most issues within the category of Issues of Power and Trust and this affects willingness to participate in a trial. Study 2 data was stronger in this category than that in Study 1, exhibited by emphatic questioning on the purpose, focus, and risks of the NET-works trial, as well as questioning why the Latinos are being invited to participate in the trial. There were additional concerns about perceived federal involvement in the trial. Also paralleling Study 1 data was considerable apprehension over the mandated reporter status of the researcher and what is considered a "reportable" offense. The data provided possible explanations for the desire to speak face-to-face to a researcher rather than by phone or accessing information via a website. To the issue of speaking on the phone,

> We don't even know who we are talking to.

And to the issue of accessing information via a website,

> I think sometimes it is not the right information to be safe. We can't take the risk just like that.

These participants needed to physically see the individual who was presenting information in order to trust that information was correct.

Autonomy. I refer the reader to Chapter 3 p. 227 to review the affect the social context just described has on the community members' ability to exercise their autonomy. The content of that discussion is unaffected by the Study 2 data.

Receiving information. The analogue participants felt they understood one or more of the following points: that home visits would happen, the study details generally, and the risks of the study. Yet, the study risks were less understood in this research phase than in Study 1. No participants in Study 1 seemed to understand why the study researchers wanted a hair sample from the children, but two analogue participants in this research phase did understand that the hair was to be used to check for a hormone that reflected stress levels. This information was not conveyed in the video, but was included in the textual consent form.

Data from Study 2 also provided several examples of analogue participants contextualizing to form meaning, that is, using a familiar experience to make sense of a new experience. These examples used the following phrases to introduce their experiences: "because I had an experience once," "in my case," and "I remember long ago." As noted by Hall (1976), communication in a high context culture such as Mexico locates information in the physical context or is internalized. As such, contextualizing principles is essential for understanding. In his research with Latin Americans, Thatcher (1999) noted a need for contextualizing applications and for developing "more narrative, drama-like structures" (p. 194). This was demonstrated in his study when participants dismissed a written document to verbally discuss the principle in order to "dramatize the norms in concrete, applicable scenarios" (Thatcher, 1999, p. 181). Contextualizing can be considered a rhetorical element of this intercultural communication.

Similar to Study 1 there were misunderstandings about various study details and about randomization and the fact that the trial had two arms. There were also misunderstandings about the risks of participation, which were not seen in Study 1. One analogue participant thought there was a risk if a child is overweight and they jump or run. This participant went on to say that if that were the case, the child would walk instead and that is the education they would receive. Another analogue participant thought there was risk of not being able to do exercise during the three-year period of the study. One analogue participant felt there was a possibility that their children would be given medicine.

Therapeutic misconception. As explained in Chapter 3, therapeutic misconception occurs when a research participant believes, "that their individual needs will determine treatment, or that the likelihood of benefit is greater than is actually the case" (Candilis & Lidz, 2010, p. 338). The implications of therapeutic misconceptions are significant in that they effectively impede an authentic informed consent. I have discussed how the study invitation letter may be partially responsible for some of the misconceptions (see Chapter 3 p. 111).

The therapeutic misconceptions of some analogue participants in Study 1 were general, thinking participation could lead to a better life, possibly improving the family's lifestyle and even their future. Other more specific therapeutic misconceptions included thinking the study was a weight loss study. One topic that emerged in the Study 2 data was very different than those heard in Study 1—child sexual abuse,

> Educate the children more in a way so that they can't be abused by anybody, something better for our kids future; not sexual abuse. These are the things that are very important because we are many families in this country affected that way and they don't report to the police.

This analogue participant was thinking that participation would include classes that teach parents how to speak with their children about sexual matters. Another participant echoed this impression,

> Speaking about sexuality we are very closed minded and we don't want to speak about this topic which is very important so our girls won't become pregnant or our boys get any sexual transmitted disease. It's very important to take family classes to learn how we can help our family.

These participants are projecting their needs onto the trial, turning the actual trial details into something that can specifically address problems they were experiencing. This topic reflects the importance of family to this community. There was another clear misconception that acknowledges problems with children stemming from too much time spent working,

> I think José's [enroller in the video] goal is for parents and kids to get family counseling; family programs because many times as parents we believe we are right and trust our children to communicate with us but in reality it doesn't happen because when we have one or two jobs we just can't pay attention to them.

The rhetorical examination of these misconceptions presented on p. 143 in Chapter 3 remains applicable. I repeat the concluding paragraph here.

With respect to the results of this study, I have shown that the analogue participants hear the presented information through the screen of their social context. As was shown in the previous subsection, the ultimate motivation for this community, the telos of their migration, is "a better life." 'A better life' is the reason they are in this country and are confronting the consequences of being undocumented. The terministic screen of "a better life" directs attention to activities that work toward this goal while deflecting attention from the harsher realities of their lives. This may explain why the

participants exhibited the therapeutic misconceptions they did by overestimating and misconstruing the benefits they would incur by participating in the public health study.

Data from Study 2 did not alter this analysis, but rather added complexity to my understanding of the social context of this community.

Justice. One analogue participant questioned, in a concerned manner, why Latinos were being recruited,

> Why are you taking Latino communities to participate in this? Why until now you are taking Latino people into consideration to participate?

Another analogue participant deemed the trial "racist,"

> Sounds very racist and he [the enroller in the video] already clarified here, he said that any federal agencies will have access to this information. So, it sounds very racist for me. Only because I don't have legal documents I can't participate in this study? It sounds very bad.

These comments reflect a suspicion that the Latino community were being targeted for participation for exploitive reasons or for reasons related to deportation. The possibility of exploitation is shown in the following statement,

> So in the video it was saying that there's support for the state, there's support for the federal government, but then we want to know is there support for the community because they're the ones who are going to be at risk. What are their benefits? Not just for the state, not just for the government.

These comments speak to the third principle of the *Belmont Report*, justice (Belmont Report, 1979, B.3.). This principle involves issues regarding who is receiving the benefits of research and who is bearing the burdens. To explicate this further I will include a section of the interdisciplinary literature review below.

The principle of justice seeks expression in the careful consideration of who is selected to be subjected to the risks of research as well as who is included in possibly beneficial research. If the research does not contain a therapeutic component, researchers should choose subjects from classes of persons that are not already burdened by societal factors. Persons from vulnerable populations should be included in research only for justifiable reasons.

However, by protecting this population, they may be deprived of possible benefits resulting from participation in clinical research. These could include either therapeutic benefits resulting from direct research participation, or benefits to a specific group. Certain populations experience higher rates of certain conditions or diseases than the overall population, therefore inclusion of these populations is essential. For example, among Hispanic adults (using an age-adjusted rate) diagnosed diabetes rates are 8.5% for Central and South Americans, 9.3% for Cubans, 13.9 % for Mexican Americans, and 14.8% for Puerto Ricans. In contrast, the rate among non-Hispanic whites is 7.6% ("Statistics About Diabetes," 2014).

Inclusion of minority members increases the generalizability of research results, while lack of participation contributes to health inequities and health disparities (Charleswill, 2014; Paskett, Katz, DeGraffinreid, and Tatum, 2003). Charleswill (2014) summarizes the importance of this situation: "The inclusion of minority populations in human subjects research may be a complex and challenging task; however, the consequences brought about by the gaps in data and information about the effects of therapeutics and other interventions on these groups are dire and of ethical importance" (p. 300).

This is an important area of inquiry. I reviewed data from Study 1 and found no other instances of this concern over justice.

Presenting information. Two statements were made that effectively summarize the problem of comprehension,

They told us but they didn't explain.

You gave me the information but you didn't explain it to me.

Presenting the information, in any format, does not ensure comprehension. I have compiled all pragmatic suggestions given by analogue participants into Table 13. Advice on How to Improve the Consent Conference—Study 1 and Study 2.

Table 13. Advice on How to Improve the Consent Conference—Study 1 and Study 2

Pragmatic Advice:
Clearly state whether "illegal" persons can participate
Communicate in a direct manner
Focus on the main points
Keep presentation short
Present the information in sections and confirm comprehension with exercises after each section
Provide a strong introduction forecasting what will be covered (This will help keep people's attention)
Use plain language
Use visuals in the explanations (To accommodate those with low literacy)
Cultural Advice:
Conduct the consent process with a group of Latinos rather than individually (Being in a group will provide participants confidence)
Confirm comprehension with exercises after each section of information
Have a face-to-face discussion (Allows for question and answer as well as stimulating interest and also prevents misunderstandings.)
Have a Latino who has or is participating in that or a similar trial available at the conference to answer questions and discuss their experience to increase an individual's capacity to trust their own decisions.
Have other family members and/or trusted community members involved in the conference.
Keep presentation short
Motivate the potential participants
Promote the trial in the church
Provide credibility by highlighting enroller's association with the University

Read all materials aloud
Send all information via postal mail prior to the meeting (Knowing the topic in advance facilitates understanding)
Shorten the consent conference and consent form.
Stress that enrollers are professionals
Use the term “study”, not “investigation”

One topic that was strengthened in this research phase was the restructuring of the conference format. Analogue participants requested that the conference and the consent form be shorter and follow the practical suggestions listed in the Table 13. They requested the information be presented verbally and they requested the opportunity to bring the materials home in order to contemplate participation. They also requested multiple meetings in order to be able to ask questions in order to clarify the information.

The amount and type of information provided to a potential participant is subject to debate. The *Belmont Report* does allow that, “a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided” (Belmont Report, 1979, Part C. 1., para. 4).

As explained in Chapter 3, there is literature that supports providing less information. Edwards, Lilford, Thornton, and Hewison (1998) conducted a literature review on different methods of obtaining informed consent for enrollment into clinical trials. The authors concluded that since autonomy is the grounding of informed consent, “a patient [being enrolled in a clinical trial] should be asked whether or not they wish any information upon which to base a decision” (p. 1839). Epstein, Korones, and Quill (2010) attempt to balance autonomy, beneficence, and nonmaleficience by allowing individuals a choice on how much information they receive. Too much information, they explain, can create a cognitive overload potentially interfering with understanding and

decision making. O'Neill (2003), in a discussion of limitations of informed consent also looks at the amount of information disclosed, "The inclusion of excessive or technical detail…will eventually overtax even the most energetic, and undermine the possibility of informed consent. On the other hand, consent that is too vague and general may also fail to legitimate action" (p. 5). Flory and Emanuel (2004) who showed more time spent with potential participants improved understanding. This investment in time would certainly improve the consent process for immigrant populations and would result in more equal sharing in power. Yet, research conducted by Edwards, Lilford, Thorton and Hewison (1998) found that more information and more time used in a consent conference resulted in lower enrollment rates. This may partially explain reluctance by researchers to employ such an approach.

As explained in the Chapter 1: Introduction, this project is attempting to inform the challenge of how to best secure, what Katz (1993) terms, a morally valid consent. Katz (1993) explains that in order to follow his recommendations to secure a morally valid consent (as compared to a legally adequate consent), takes time and "may have to extend over hours, perhaps even days, and must be continued until one is reasonably certain that the patient-subjects understand" (p. 36). This investment in time would certainly improve the consent of immigrant populations, by demonstrating a concern for the individual and the willingness to have a conversation; a more equal sharing in power. This would provide an environment where questions could be asked and concerns aired. Sherwin (1998) also makes the point that obtaining informed consent that truly protects patient autonomy is time consuming.

This is consistent with the recommendation presented in Chapter 3, subsection "Promoting autonomy" (p. 151), that researchers consider themselves educators rather than authorities. Warren (1998) explains, "Teachers need to repeat, to connect with this student's experience, and to get feedback from students so that inaccuracies can be corrected. Teaching skills are hard-won—requiring practice, experimentation, and

sensitivity to audience. The medical model downplays the difficulties of teaching well, tends to attribute failures of communication to patients" (p. 82).

Persuasion. An emergent topic in this data was a request for a persuasive element in the consent conference. Analogue participants referred to this as "motivation" (*motivar*) or "convincing" (*convencer*). The following comment incorporates several significant issues that have been identified in this project. There is a request for motivation (get me motivated, convince me), an acquiescence to status (I will…sign the programs you believe are good), a belief that the consent form is too long (there are too many pages), a request for assistance in understanding the material (someone takes the time to go through it), and a demonstration of the cultural value of family (do the right thing for the well-being of the family),

> Because you are not explaining to me what you want to archive. I know you are talking about health but get me motivated and clarify what you want us to do if my children get involved and are the right age. Convince me and show me this program is for good and I will be happy to sign the programs you believe are good for the kids. We as parents, declare the food at school is not good but also, we have to search for information by asking someone. So, again, if the person is interesting and comes to me without explanation or motivation, I can't sign because there are too many pages that I don't know if there is a useful information but if someone takes the time to go through it then I can take a time to do the right thing for the well-being of the family.

The request to be "motivated" or "convinced" is interesting from a rhetorical perspective. There exists unmistakably the potential for unethical persuasion.[26] Segal (2005) notes, "two people are not engaged in a properly rhetorical enterprise but rather, perhaps, in a coercive one, when only one of them really knows what they are talking

[26] For a discussion on the distinction between *persuading* and *convincing* see Perelman and Olbrects-Tyteca (1969), p. 26.

about, and the other only knows what the first one reveals" (p. 18). There does exist an ethical persuasion; for this to occur the researcher must take the time to thoroughly explore the rhetorical situation. The rhetorical situation of this community is what I'm calling the social context. The researcher must thoroughly understand the social context of the population they are recruiting and also understand the cultural designation of the researcher's *êthos*. The researcher holds a high status, which may cause some wariness from the community members but the researcher's knowledge will be unquestioned. The discussion of Burke's theories of division and identification are instructive for connecting with this specific audience. The next chapter will describe the third study in this project.

Inter-text

Managing her diabetes

My family has it. My grandfather died from his high blood pressure and it's now that I see the word stroke. So now I have been trying how not to eat a lot of salt to control my high blood pressure. And now I do not have cholesterol, and all of the medicines that they gave me, I stored them because they irritated my stomach. It was with only natural remedies like oatmeal every day. I had oatmeal with an apple daily. That was to control my cholesterol. But for controlling diabetes, no. I try to do exercise and go out and such, but sometimes I just don't even have the desire to do anything, nothing whatever. And to top it off my children tell me, "you have to go out to walk, you have to" but I don't even have the desire to go out. When it goes up, it's bad. When it goes too low, then I'm like this.

So then, see it's much better to carry my pills in my purse. I have to take, I counted how many pills I had to take, and I was taking 10 pills a day. I felt my stomach inside out.

So then, I decided not to take the cholesterol pill and some vitamin pills because they had prescribed vitamin D and C, it was just too many pills. And they are huge pills like this. So I try to more or less have variety in the foods I eat and nothing extra and only take the pills in the morning. I take a pill at night if I need to lower it. And the other half I take at noon day. But see, taking three pills is different compared to taking 10 pills. However, it is difficult living with diabetes. It is very difficult. It's because you see things and you want to eat them all. I have weighed up to 400, 300, almost 400 pounds. It's something that even your head hurts severely, you feel faint, and you feel bad all over. It all ends with it finally lowers or it regulates itself, and then your sore all over where your legs hurt, your arms are like this, and you don't know what to do. It's awful. It's awful living with diabetes.

Chapter 5: Study 3

Methods

Quien canta su mal espanta.

He who sings frightens away his grief.

In this section, I describe research methods that differed from those detailed in Chapter 3: Study 1 and Chapter 4: Study 2 and do not go into detail on those matters that remained the same in this research study except when needed for clarity. The significant difference was the topic of the presented trial; this research Study used a diabetes trial for the simulation. As previously noted, Latinos present high rates of type 2 diabetes (Caballero, 2005). Many of the analogue participants in the first two studies of this project discussed this medical condition and its effects on themselves and their community—it is a familiar disorder.[27] This change in trial topic was important to more deeply examine the informed consent process by looking at a consent conference for a medical trial, in this case a diabetes trial. Moreover, the Chair in Diabetes Research in a large Midwestern university's medical school granted permission to use the consent materials from a recent diabetes trial she conducted, Action to Control Cardiovascular Risk in Diabetes (ACCORD).

An enroller from that study conducted a "typical" consent conference that I audio recorded. The recording was transcribed and translated to produce a script. I had originally proposed making a video using this script, similar to the video used in Study 1 and Study 2. This video would be shown to members of the Latino community at the location used in research Study 1. After viewing the video, the analogue participants

[27] For a complete description of diabetes mellitus provided by the American Diabetes Society see: Diagnosis and Classification of Diabetes Mellitus, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2613584/.

would participate in a semi-structured conversation in the same manner as the previous phases, discussing their impressions of the video, the presented information, and the ACCORD informed consent form. I submitted a "Change of Protocol" form yo my institution's IRB requesting approval to show this video in place of the original two videos from Study 1 and Study 2 on July 15, 2014 and received approval on July 28, 2014.

As I began to arrange for focus groups, I reconsidered the use of the video and instead decided it would be preferable to read the conference script to the participants. The diabetes trial was very complicated, much more so than the healthy patient study used in the first two research phases. I felt that if the script was being read, I could easily stop at logical points (these stopping points would be predetermined and used consistently) and ask for questions and concerns from the participants. I could then audio record the participants' thoughts at each stopping point. If the participants waited until the end of the video to ask questions, I was fairly certain some would forget many of their questions and comments because of the complexity and length of the video. I also considered that it would be easier to revisit a portion of the script verbally rather than attempting to find a certain spot on a video. The simulated consent I recorded with the trial enroller took 55:07 minutes to complete. (I will discuss this length later in this section).

I then submitted another "Change of Protocol" form on September 24, 2014, explaining the only change from the previous request would be the medium being used: a person reading the script rather than a video of a person reading the same script. The methodologies (grounded theory, analogue participants); the pool of potential participants, and the study location remained the same. I also requested approval to offer

$15 cash versus a $15 Cub Foods gift card to thank participants for their time.[28] I received approval for these two requests on October 28, 2014.

Location. This research phase took place at the urban Catholic Church that was used for Study 1. I began corresponding with the parish administrator approximately a month before the actual focus groups to set dates and talk about the logistics, such as available rooms. The focus groups were held on November 9, 2014 after the 11:30 a.m. Mass and the 1:15 p.m. Mass. An announcement of the upcoming research was given after the 11:30 a.m. Mass and the 1:15 p.m. Mass the week before. Flyers were also distributed (see Appendix T).

Research design and methods. Study 3 utilized the ACCORD diabetes trial enrollment script translated into Spanish (see Appendix U) and the textual artifact, the informed consent form translated into Spanish (see Appendix V), as the stimulus. The focus groups took place directly after mass in the lower level of the church. The interpreter invited people to participate at the end of each service.

[28] This change from a gift certificate to cash was needed due to an unexpected event. Some cards were deactivated due to a confusion with the bank, who mistakenly thought the purchase of these cards was fraudulent. Some of these deactivatedcards were distributed after one of the focus group sessions. When I learned this I brought new cards for those participants, but a level of trust was broken. Since Study 3 had the potential of being conducted with the same community, it was necessary not to continue to use gift cards, but rather offer cash. The monetary amount remained the same.

Figure 11. Focus group room

Figure 12. Meal in focus group room

At the start of each focus group, I invited everyone to help themselves to the meal. The children took their plates and went with a Spanish-speaking babysitter to another room in the lower level. The analogue participants were asked to be seated around the table. I then thanked the participants for coming and explained the intent of the study. The analogue participants were given this study's informed consent form (Appendix G). If requested or if we sensed it necessary, I, or the interpreter, read the consent form aloud in Spanish to aid those with low literacy. At this time, any questions or concerns were addressed, and the analogue participants were asked if they would like to continue with the study. Though mention of audio taping the interviews had been made in the consent form, I reiterated that procedure and asked if the analogue participants were comfortable with the taping. I explained that I wanted to hear everything they had to say and it would be difficult for me to remember our conversation without the tape. Signatures were not required on the consent form (via permission from

IRB), although I offered each participant a copy to keep for their records. I then administered a short demographic questionnaire (Appendix H), reading it aloud for any individual I felt was struggling with literacy. I did not administer "The Short Assessment of Health Literacy for Spanish Adults (SAHLSA-50)" questionnaire for two reasons. One was a consideration of time. The consent script was quite long and I knew we had time constraints. Additionally, other than a suggested correlation between low levels of education and low SAHSLA scores, little additional information had come from this instrument.

The script that was used as the stimulus was an adaptation of the consent script that was created from the recording of the enroller's simulated consent. The entire simulated consent lasted for 55 minutes, which was much too long for this population. Within the consent form was an extensive list of all possible medications that could be used in the actual trial (some 20 drug groups) along with their potential side effects. I removed this list and marked logical places that we could stop reading and ask for questions or comments. A full description of the script is provided in the Results section. See Appendix W for the revised script.

Prior to reading the script, I briefly defined the concept of clinical trials and explained the concept of being an analogue participant, specifically that they were pretending to be in a consent conference. There was blank paper and a pen on the table for each participant and I invited the participants, if they chose, to take notes during the reading of the script to help remember their thoughts. The analogue participants were next given the ACCORD consent form to consult while listening to the explanation (the revised script). I read sections of the script, stopping periodically to hear questions or comments. These interactions were audio recorded. At the end of each focus group, the participants were thanked and given $15 to thank them for their time. A total of 30 people participated in the two focus groups.

Data analysis. All audio recordings were transcribed and then translated into English. Possible limitations and complications that might arise from translating from one language into another will be addressed in Chapter 7: Implications, Research Quality, Limitations, Future Research. This phase of data gathering employed theoretical sampling, which is used to refine the theoretical categories by elaborating their properties. Glaser and Strauss (1967) define theoretical sampling, "Theoretical sampling is the process of data collection for generating theory where by the analyst jointly collects, codes, and analyzes his data and decides what data to collect next and where to find them, in order to develop his theory as it emerges. This process of data collection is controlled by the emerging theory" (p. 45). There is some variation of the definition of theoretical sampling among contemporary researchers who use grounded theory. For example, Charmaz (2006) believes categories need to be identified before using theoretical sampling, "Because you intend to use it to elaborate and refine your theoretical categories, conducting theoretical sampling depends on having already identified a category(ies)" (p. 103). I am most closely following the Glaser and Strauss (1967) conception of theoretical sampling and the Charmaz (2006) approach.

I first coded the transcripts using the initial codes from Study 1 when applicable. When new codes were needed I examined the existing categories for applicability. Through memo writing I was able to elaborate the properties of two categories in meaningful ways. The data from this phase of research is reported in the next section, Results.

Results

No tengas como vano el consejo del anciano.

Do not consider useless the advice of an old person.

Demographic data (n=30).

Table 14. English Fluency Study 3

	English Fluency* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 3	24%	0–>12	50	10–24	16

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

Table 15. No English Language Skills Study 3

	No English Language Skills* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 3	64%	0–>12	40	11–30	14

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

Of the 30 analogue participants, 25 completed a Demographic Data Form (see Appendix H), though some forms were only partially completed. A complete listing of the raw data can be found in Appendix X). Of the 25 completed forms, five individuals (24%) reported speaking English fluently (with a score of 4 or 5, with 5 signifying fluent English language skills). While two of the five reported having more than 12 years of education, two reported 7–9 years of education, and one reported no formal education. Two of the individuals reported an age range of 36–45 years, two reported an age range of 46–55 years, and one reported an age range of 55–65 years. All individuals had been in the U.S. for at least a decade, with the range for all individuals being 12–24 years in the U.S.

Sixteen (64%) of the analogue participants reported very little to no English language proficiency. Interestingly there were no participants in this research phase reporting a moderate level of English language proficiency. Education levels were fairly low for these individuals, with nine reporting 0–6 years of education (of these four reported no formal education), five reported 7–9 years of education, and two reported more than 12 years of education. Three of the individuals reported an age range of 26–35 years, six reported an age range of 36–45 years, three reported an age range of 46–55 years, three reported an age range of 56–65 years, and one did not report an age. Fourteen of the 16 had been in the U.S. for at least a decade, with the range for this group being 11–30 years in the U.S. Two of the 16 had been in the U.S. for 5–10 years.

Finally, 17 of the individuals named Mexico their country of origin, three reported El Salvador as their country of origin, and three reported Ecuador as their country of origin.

Consent form and consenting script.

Action to control cardiovascular risk in diabetes (ACCORD)

This consent form is 16 pages long. The form says, "You are being invited to participate in ACCORD because you have Type 2 diabetes along with other factors that increase your chance of having future heart disease and stroke, or you may already have had heart disease or stroke" (Appendix V). I will now briefly list the content of this document.

- Background Information: This section explains the study purpose and length.
- Procedures: This section begins by describing the screening visits. If you are found to be eligible and you agree to participate in the trial, the document explains that you will be put in one of two arms, though it doesn't use this term. Your blood sugar (diabetes) will be treated and either your blood pressure or your blood lipids (cholesterol) will be treated according to the ACCORD protocol. The document then explains the blood sugar treatment groups saying you will be assigned to one of two blood sugar goals. You will then either be assigned to the blood pressure treatment group or the blood lipid treatment group
- Genetic research is part of the study. You can volunteer to take part in this component.
- Visit schedule and measurements: This section explains expectations in detail.
- Potential risks of participating in the ACCORD study: This section explains the possible risks including the side effects of every possible medication family that could be used in any arm of the study (20 drug families). Drug interactions are discussed at the end of the section.

- Potential Benefits: This section explains there will be no charge for any of the required tests and procedures performed during the study.
- Alternative treatments: This short paragraph says if you don't participate, go to your personal doctor.
- Research related injury: This section there is a small risk of injury. If that should happen treatment will be available, however it will be billed to you or your insurance company.
- Confidentiality: This sections details how your health records connected to this study will be handled. This includes a U.S. Federal Certificate of Confidentiality.
- Voluntary nature of the study: A brief paragraph saying you can leave the study at any time and the study doctor has the right to stop your participation.
- New information: This short section tells you that you will be given any new information gained during the study that might affect your health or welfare.
- Questions about the study: This is contact information.
- Genetic studies: This section provides details on this optional part of the study.
- Participant's agreement for the genetic portion of ACCORD: Check boxes.
- Participant's agreement for ACCORD study: Signatures

I was provided with a PDF of the actual consent form that I converted to a Microsoft Word document. This document showed a Flesch Reading Ease of 45.5 and a Flesch-Kincaid Grade Level of 11.7. However, the program transfer contained many errors. I did transcribe the verbal consent conference conducted by an ACCORD enroller. This transcript followed the consent form quite closely. I used this transcript to obtain an estimate of the reading level of the consent form. These levels were, Flesch

Reading Ease of 49.1 and Flesch-Kincaid Grade Level of 13.1. This may be a more accurate assessment.

Categories. The majority of the results from this research phase are contained within the existing category Community Health. I will present these results within a subcategory. There is also data that elaborates the properties of the categories Understanding, Misunderstanding/Not Understanding, Presenting Information, as well as indicating the need of a new category, Trial Design, which is necessary to account for the principal of justice, as defined in the *Belmont Report* (1979). The data also provided additional insights for Research Question 4 (What facilitates participation for this population?) and Research Question 5 (What restricts participation for this population?).

While I planned to get through the entire revised consent script during the focus groups I was not able to do this within the allotted focus group time of one hour. The portions of the consent script that were read provoked many questions about diabetes including questions about symptoms and causes. The *in vivo*[29] code "is it true?" was prevalent. The questions about diabetes are listed in Table 16. Questions about Diabetes.

Table 16. Questions about Diabetes

What are the diabetic symptoms?
Do people with cholesterol issues result with diabetes?
What is diabetes Type 2?
So is it true their eyesight is affected once they start on insulin?
So, once they start using insulin, is it true that they go blind?
So it, diabetes, can show up in different ways?
I want to know the right levels [blood sugar levels] when you have diabetes and when you don't have diabetes.
How is that, that people have different levels?
What causes diabetes?

[29] *In vivo* (Latin: in a living thing) codes use participants' words to name a larger concept in the data.

How many different types of diabetes are there?
Like insulin, for example. There are people who have to get insulin injections, right?
So how true is it that it's more likely to happen when someone is overweight?
Then the skinny ones don't get it?
Does that [insulin and pills] affect any organ in the body like the liver or kidneys?
Can upsets and frights provoke diabetes?
But I would like to know what the symptoms are?
When does someone start feeling diabetes or something like it, just to be aware?
But is there a way to control it [diabetes] without medication or not?
I want to know what are the symptoms that you are talking about with respect to the heart.
When a person is a diabetic, so like they have the need to inject insulin, what is the benefit or damage from insulin injections?
But that [stroke] happens to the person when their sugar levels are too high?

I examine the questions in this table in the next section, Discussion.

Community health: Navigating care. I am creating a subcategory of Community Health and labeling it Navigating Care. This subcategory includes codes dealing with insurance, treatments including conventional and natural remedies, cultural bound syndromes, family involvement, and compliance. This subcategory was by far the most prevalent within the Study 3 data. I provide a description of each of these initial codes, in no particular order. In Chapter 5 Discussion, I will indicate their significance and their inter-relations.

Insurance/expense. There were many concerns vocalized around the topic of insurance. One topic of confusion concerned whether an individual would be allowed to participate in this study if they did not have insurance,

> Oh. So for those of us that do not have it [insurance], what happens? We can't participate?

Some wondered if there is a fee associated with participation and wondered how they might know what the cost would be. One participant mentioned his clinic gives uninsured patients a discount.

Even those with insurance were concerned. One participant told a story of an accident she had experienced and said the insurance did not pay anything on the medical bills resulting from the accident. Since she is still suffering from symptoms, she needs to go to the hospital fairly often. She connected the stress from those bills to her continued pain,

> You know I make payments, even though it takes me a while to pay it off but I pay, pay, pay. And that's the reason why I am like this with the pains, Just from thinking about it.

Another participant also said he was making payments on medical bills. He made regular payments because he did not want to be sent to collections and did not want a bad financial record. One participant wondered if their insurance would pay for both her regular doctor's visits as well as the study costs. Some of the analogue participants had insurance, some did not. One individual said they had Medicare. Others discussed ObamaCare. They correctly noted that ObamaCare requires individuals to have insurance, however they would not be acquiring insurance because it is too expensive.

To clarify these questions I communicated with the enroller who went through the informed consent form with me. Her reply was,

> No insurance needed. Having a primary care physician was recommended, although not required. We were clear that we were not managing things other than their diabetes, blood pressure and/or cholesterol. Although, I can tell you from my own experience that we did

> not ignore health concerns of our subjects as they came into see us so regularly. Cost is such a difficult barrier to health care!
>
> We did not offer transportation unless a subject had a specific concern about it (couldn't get to appointment because they did not have a ride). We did have funding available if necessary, but it rarely came up.
>
> As far as undocumented are concerned—I don't think anything would change if they were found to be undocumented, however social security numbers are generally required for studies in which there is reimbursement involved. I believe SS #'s were required to reimburse for the test strips (personal communication, July 24, 2014).

Treatments including conventional and natural remedies. Many analogue participants shared their own experiences with diabetes. Several of these individuals were under doctor's care and had their diabetes under control. One participant shared that he had experienced high cholesterol in the past, however he changed the way he ate, and he exercised and as a result lost a considerable amount of weight, lowered his cholesterol. The need for proper nutrition and exercise was acknowledged by some as the necessary steps to control diabetes along with the correct medication and regularly checking one's blood sugar. As shown in the initial code Family Involvement below, children urge their parents to exercise.

One analogue participant mentioned the clinic she goes to where she attends a weekly session to get nutritional advice. Other participants asked her for details so they could also attend. Several individuals said they had been diagnosed with "pre-diabetes." One analogue participant said since she has pre-diabetes so she now needs to see a nutritionist to learn how to eat properly,

> So I went to a nutritionist. I talked to her and she gave me some steps I have to follow. So like tortillas, I do not eat anymore. As also, uhm, regular sugar, well I never, you know I stopped using it a long time ago.

> But my brother is diabetic. My dad recently died from diabetes. So then now, they just told me that I am pre-diabetic. So what I do now is go out for walks.

An example of the use of alternative medicines was given by another participant who described an accident she had that resulted in reoccurring headaches,

> Because of the fall, when I hear a lot of noise, this ends up like this and it goes like a throbbing sensation, throb, throb, throb. I am not well every day because of those pains. But I try to take a pill I have, they send me from Ecuador. It makes me feel better, along with some creams, and then I can work. I can work and work and work with only the aid of the cream and that pill.

Finally, another participant described not taking the medication she was given to combat high cholesterol because it hurt her stomach. Instead she eats oatmeal with an apple daily to control her cholesterol. This is also an example of non-compliance.

Folk illness (susto) *and the role of faith.* This following story is illustrative of many things, but most interestingly of the folk illness called susto, translated as "fright." Folk illnesses are cultural constructions of psychological afflictions, often with physical symptoms. The folk illness *susto* appears in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) as a Cultural Bound Syndrome.

This story is also a narrative of one woman's journey with diabetes including its etiology (*susto*), issues of noncompliance, symptoms, and treatments. This narrative will be unpacked and examined in the Discussion section of this chapter,

> Yes. See, I am from El Salvador but I lived in Mexico. Since I worked in the evenings, I was assaulted. It made me very scared so I was in a state of shock (*me asusté*). So then a woman gave me two big, like this, glasses of water to drink. It's a remedy for a fright (*el susto*). But that's

the worst thing that people can do when they have a fright (*un susto*). Then in the nineties, from there I came to the U.S. They told me that I was pre-diabetic and gave me some medicine. I thought this doctor was crazy, since I never…don't even come from a diabetic family. So then I was considering what the fright (*susto*) had to do with it. But since I didn't take the medicine, I decided to just leave it and started working at a fabric warehouse. I wanted to lose weight by wrapping myself with plastic, because I was big, not very big, but somewhat big. So then I started losing weight and more weight. And a co-worked asked me what I was doing since I had lost a lot of weight. And I told her that I didn't know. From there she took me to the doctor. My sugar reading was at 500. Super high that the doctor got shocked (*se asustó*). They had asked what had happened and I told them that I didn't know. I had an uncontrollable thirst that I would buy Coke and drink, and drink. I would also not even sleep because I would spend most of the time in the bathroom. And the doctor told me they are going to give me an insulin injection and that I was going to feel better. It was insulin that was able to control it for me. But during that same time, I had had a very big problem with my husband that I drank water again and that was bad [referring to the fact that drinking water for a susto is ill advised]. So then most recently, could be because of the weather or because I work a lot, my knees started hurting. So they gave me cortisone injections and cortisone raises the blood sugar. So I could only have insulin. Right now I am taking insulin. It is 8 units of insulin every 24 hours due to the fact that I cannot control it with pills. So then I am going every Wednesday to a meeting for diabetics at, it's a clinic. They are showing us what to eat there. So now, like how is it, I have lost weight because I no longer eat greasy foods and now I eat more vegetables. And that helped lower my cholesterol. But it is so close. So like right now, I live in St. Paul. I have a problem with my baby sister that I get a severe headache that it hurts right here and even my mouth gets all dry. So then my sister says to me like she is a believer in the churchy things. She says do what the prophet

> so and so says if you see the bad, then you should flee from it. So if you see that is what is affecting you most, then that's what she says. My husband is right now in the state of Washington so right now I don't have that problem. You know, he drinks and all that. We would also fight like cats and dogs. It was the same story. But in that regard, I am at peace now. After living with my niece, I decided to move back to Minneapolis and try to control my sugar. Right now I am having to take 8 units. For now, I have been waking with sugar reading of 90, 105, it has not gotten any higher. But last time we had problems, it was in the 200s. So it's my opinion that frights (*sustos de corajes*) and things like that are the cause of it [diabetes].

In another conversation, an analogue participant described a person they knew who had kidney problems, but since that person was undocumented "they" would not operate on him,

> Thanks to God, it appears that God has healed him that he no longer needs the operation.

Responding to this story another participant responded,

> Praise God for that, right? But because of no documentation they do not want to perform a surgery on an individual. Just imagine, since we don't have documentation, will they even want us involved in this [the trial]?

This comment also pertains to the principle of justice, listed below.

Family involvement. There was evidence of family members being of great importance in the participant's lives and supporting participants in managing their diabetes. One analogue participant, a woman, while describing the results of her doctor's appointment for diabetes said,

> So that's what I told my children, since I tell them everything.

She then described her daughter's angry reaction to the doctor's diagnoses, with her daughter reminding her that her children work so she doesn't have to, they have signed her up at the gym, of which she doesn't go, and have asked her to just go outside and walk, which she won't do. The diabetic mother then resolved to be more compliant,

> From that week, I made a commitment so that when they rechecked me it went down, down, down, to 150, 120, a hundred like that…with that, little by little, I was able to reduce it without taking insulin.

Another woman told her etiology story of diabetes. She felt that her diabetes was caused by chocolates. She explained that she quit smoking by eating chocolates, which caused her diabetes. She knew that smoking was worrisome for her daughter, who systematically destroyed her mother's cigarettes,

> My daughter, geez, always my daughter[30]

Another analogue participant, a diabetic, described being worried about her husband's health. The wife very much wanted to check husband's blood sugar with her glucose meter, however she and her husband both heeded her doctor's advice not to do so.

Compliance. There was evidence of both compliance and non-compliance to medical advice in the data. The Inter-text "Managing her diabetes" provides an example of non-compliance. This analogue patient did not like taking the many medications, including vitamins, that had been prescribed for her. Additionally, these medications irritated her stomach so she made the decision to stop taking all but the diabetes medications.

There were also several examples of compliance with analogue participants saying they followed what their doctor's advice and lowered their blood sugar levels.

[30] What I've translated as "geez" is the word "híjote" which is a derivative of "hijo de puta," literally "son of a whore."

One woman explained that even though her husband followed the doctor's advice, he still appears ill. She explains he is very tired and goes to sleep because he is dizzy, despite doing what the doctor suggests,

> And he exercises, he takes care of himself, you know. He follows everything the doctor has given him, everything. So like in the very beginning he had to take insulin. Now he does not take it because he follows everything the doctor has given him.

The following data enriches the current categories of Understanding.

Understanding: Contextualizing. Similar to what was found in Study 2 there were several examples of analogue participants contextualizing to form meaning that is, using a familiar experience to make sense of a new experience. For example, one analogue participant offered a short story of her mother who suffered from diabetes and had sores on her feet, which was very difficult for her. Another participant introduced his struggle to get his blood sugar levels to go down with the phrase "Take my case."

Therapeutic misconception. There was only one instance of therapeutic misconception from an analogue participant who did not have diabetes but thought they would participate in the trial as a preventative measure,

Presenting information. As with Study 1 and Study 2, analogue participants were confused with the concept of randomization,

> How randomize? So as a participant, who decides for me in which group I will be placed? Is it the intensive or in the, I mean…in the normal one?

Some participants used similes to understand,

> It's like a drawing?

One participant made a suggestion that had been heard in the other research phases,

> Use more simple language, and then the Latino people can understand it better.

Clearer explanations were requested on whether participants needed to be documented to participate or needed to have health insurance to participate. Also, requested was a clearer explanation on the genetic portion of the study,

> Explain more about genetics study how you're going to use our blood. Make it more clear to Hispanic people.

Trial design: Justice.

> What is important is our health.

There was data that directly spoke to the third ethical principle of the *Belmont Report* (1979), justice . This principle involves issues regarding who is receiving the benefits of research and who is bearing the burdens. One analogue participant asked,

> The issue, is this study for the benefit of the medical community? Or is it a benefit for the community itself? Why? Because we are paying. If we participate, then we are paying for the study because you would be charging us, right? So the main idea is for us to help our in the study?

Another participant said she would not participate because it was,

> Like the bunnies from India, right? It would be that.

When asked what that phrase means she said,

> They use you like rats for inventions.

In other words, the researchers would be using her as a guinea pig. Related to issues of inclusion, another analogue participant noted,

> Of course they will probably would not accept us because we do not have documentation.

Though not necessarily related to the principle of justice, but certainly a matter of ethical concern is the conflict of interest mentioned,

> In addition, many studies that are done are for the very same companies that produce the medication.

R4: Facilitating participation. In both focus groups the analogue participants were asked if they would participate—about 1/3 raised their hands.

R5: Restricting participation. Reasons that would prevent analogue participants from participating in this clinical trial included:

- No time due to work commitments
- Feeling like one is being used as a guinea pig.
- The use of needle.
- The length of the study
- The requirement to check blood sugar eight times per day
- The genetic component may go against the religious beliefs of potential participants[31],

  > It is for reproduction and that is against God because only God can do that.

  > For us, I am Catholic and I know that is wrong.

- Not understanding if undocumented people can participate.
- Worried immigration might have access to study participant's information.
- No insurance.

[31] Several participants misunderstood the genetic component, thinking the researchers would use the genetic material for cloning.

- Lack of transportation.

The conceptual framework was revised to reflect this additional data and is provided on the next page. In the next section, Discussion, I examine the implications of this data.

Conceptual Framework Study 3

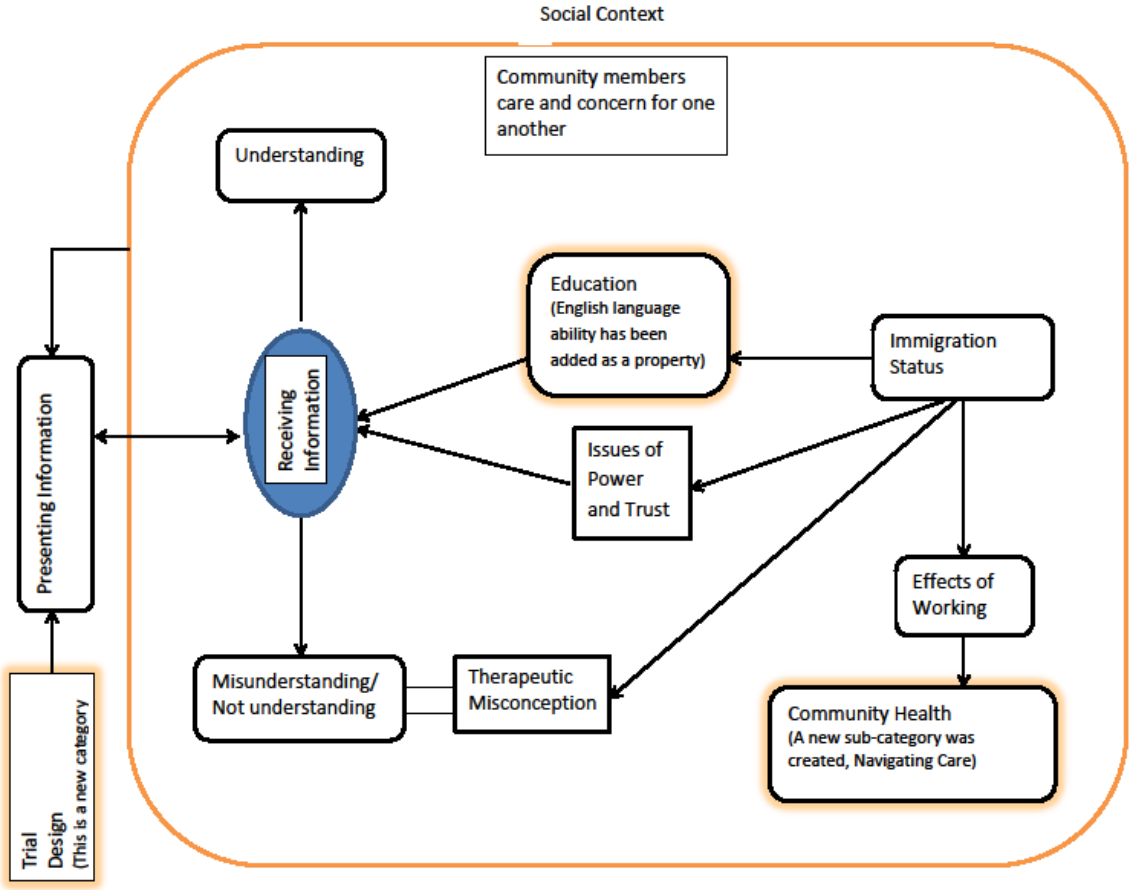

Figure 13. Conceptual framework—Study 3

Discussion

Si Dios quiere.

If God wills.

When the data from Study 3 is considered, the answers to the research questions and the grounded theory are refined. The grounded theory is reported in Chapter 6.

R1: What do Latino immigrants understand from the informed consent process?

The participants in this study understood, within the context of a simulation, they are being invited to take part in a clinical trial. What details were understood varies among participants. Least understood was the concept of randomization. Therapeutic misconception was evident; participants perceived personal benefits that were greater than the actual possible benefits or were specific to their individual needs.

R2: Is there information important to the participants that is not being communicated?

Participants requested further information on study details involving visits to their home and further qualification on the mandated reporter status of the researcher. They requested assurances of confidentiality and clarity on the risks involved. They wanted clear communication on whether undocumented people can participate in the trial. In the case of the medical trial, participants wanted information on the disease.

R3: How adequate is the structure of the conference?

> This question is best answered by Table 13, the suggestions given by the participants on how to best present this information to Latinos. Many suggestions were pragmatic and reflect some standard usability guidelines: keep the presentation short, provide a strong introduction forecasting what will be covered, communicate in a direct manner, use plain language, focus on the main points, and use visuals in the explanations. Some advice was specific to this culture: clearly state whether or not undocumented persons can participate, hold the consent conference in a group, extend the conference into several meetings, read all materials aloud, prepare potential participants by sending materials in the mail, advertise in a local community paper, promote the trial in the church, have Latinos who have been or are currently enrolled in the study attend the consent conference to provide a testimonial, and motivate the potential participants.

The researchers should promote the autonomy of potential participants by approaching a conference as an educator. The conference should be approached as a process with the investment of time and a goal of individuating the amount of information presented.

Several analogue participants said the conference should convince or motivate them to participate. They wanted the researcher to show enthusiasum about the trial and demonstrate an interest. When persuasion is used in a trial conference the researcher should thoroughly understand the rhetorical situation (social context) and the cultural designation of the researcher's ethos to insure an ethical recruitment. The researcher can be enthusiastic while still conveying the necessary information, stressing the voluntary nature of participation, and working toward the best possible comprehension.

R4: What facilitates participation for this population?

Community members were interested in participating in studies that address issues that are relevant to them or their community. They looked at how they or their family might benefit from participation; at times overestimating the benefits they might receive (therapeutic misconception). Monetary compensation was important for some, an educational component was important to most. That the trial would benefit as many community members as possible was an important consideration.

R5: What restricts participation for this population?

Anything that may expose a participant as undocumented restricts participation, such as the mandated reporter status of the researcher restricts participation. This included a general distrust of the enroller or the study. Research involving family was often approached cautiously. Another deterrent for this community was a lack of time due to work responsibilities. A lack of education could interfere with understanding. If it was not clear to the participant what the study entails they may not agree to participate "because if I don't understand I won't sign."

Further factors that may restrict participation include medical requirements of the trial and trial objectives that conflict with religious beliefs.

This section will describe what was found in the Study 3 data and how that data strengthened and confirmed the existing categories. Refer to Fig. 14 at the beginning of the Chapter 5 Discussion for the modified conceptual framework that visually displays the modified grounded theory. The colored outlines around a category indicate that the

properties of that category were elaborated in this research phase, at times changing the category's name. The category Trial Design is new and will be explained below.

I have included English language ability as a property of the category Education. No English language ability affects all aspects of this community's lives. It can cause isolation, limit job opportunities, limit involvement in their English-speaking children's lives. Ortega, Rodriquez, and Bustamante (2015) point also to the effects on health, "For Spanish-speaking populations with limited English proficiency in the United States, language barriers can affect the quality of care due to poor communication with physicians and health care professionals (78). As a result, there may be deficient or inaccurate transfers of important information, such as details of disease symptoms, the consequences of treatment or lack of treatment, and medication regimens, all of which may lead to ineffective disease management or prevention (34)" (p. 529).

Historical context. The Study 3 research was conducted in November 2014. In addition to what was described in the Study 2, subsection "Historical context," there was considerable media coverage on Central American unaccompanied minors crossing the Mexican-U.S. border,

> Administration officials said 47,017 children traveling without parents had been caught crossing the southwest border since Oct. 1, a 92 percent increase over the same period in 2013. Most are coming from three Central American countries: El Salvador, Guatemala and Honduras. More than 33,000 minors were apprehended in the Rio Grande Valley of Texas (Preston, 2014).

The main impetus for this situation was the considerable gang violence that was occurring in the home cities and towns of these children. There also appeared to be a perception in those countries that the current administration would allow the children to stay. The Pew Research Center ("More prioritize border security in immigration debate," 2014) gathered the following public opinion statistics on how to manage these children:

Most OK with Children Joining Families; Schools, Gov't Facilities More Divisive

% favor allowing Central American children illegally in U.S. to _____ while cases are pending...

	Join their families living in U.S.	Attend U.S. public schools	Be housed in gov't facility in U.S.
	%	%	%
Total	69	56	51
White	67	51	49
Black	73	65	58
Hispanic	79	78	59
18-29	80	72	60
30-49	70	57	51
50+	63	48	47
Republican	57	40	40
Democrat	80	71	61
Independent	68	54	50
Among Rep/Lean Rep			
Tea Party	43	22	29
Non-Tea Party	62	45	44

Survey conducted August 20-24, 2014. Whites and blacks include only those who are not Hispanic; Hispanics are of any race.

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Figure 14. Public opinion statistics on how to manage unaccompanied children

Additionally, mid-term elections had taken place just days before these focus groups, resulting in the Republicans retaking the Senate, with 54 seats versus Democrats' 46 seats ("Senate Election Results," 2014). President Obama was, at this time, asserting that he planned on taking unilateral action to overhaul the immigration system. In response, the Republican leadership was threatening a possible budget battle that could lead to a government shut down (Parker & Shear, 2014).

Social context. The following discussion describes how Study 3 data impacted the composition of the Social Context as well as the categories of Presenting Information

and Receiving Information. A new subcategory, Navigating Care, was identified as well as new category, Trial Design.

Health insurance. The majority of the Study 3 data fell within a sub-category of Community Health. This sub-category is named Navigating Care and describes issues concerning health insurance, diabetes treatments, family involvement, and compliance to medical advice. Navigating the U.S. medical system is often confusing and frustrating for members of this community. A practical barrier to accessing proper care is a lack of health insurance, which is pervasive among undocumented Latino immigrants, with an estimated 57% without insurance (Ortega, Rodriquez, & Bustamante, 2015). This is higher than the number of uninsured among documented Latino adults (legal residents or citizens) which the Pew Center estimates at 28% and higher than the adult population in the U.S., which is 17% (Livingston, 2009).

The analogue participants in this study spoke about the cost of insurance and the expense of what is not covered. The stress resulting from worry about making payments causes physical symptoms in some,

> You know I make payments, even though it takes me a while to pay it off but I pay, pay, pay. And that's the reason why I am like this with the pains, Just from thinking about it.

There was no mention of insurance in Study 1, however there was conversation about health insurance in Study 2,

> Yes, because to us is very difficult to get health insurance and then us as a culture we don't have the habit to check ourselves in a regular basis, only when we get sick we are going to the doctor and unfortunately once we get the third age [old age] is when we get all these sickness together that could be prevented but we don't have the same health habits compared to other cultures.

This analogue participant goes on to say,

> The doctors said, it is just matter of time and the other thing is the health insurance we don't have. We are going to discount places or until we get the insurance which takes lot of time consuming going around and we just let it go.

This is in line with data provided by the Pew Research Center who reports that 41% of undocumented Latinos report their provider is a community center. "These centers are designed primarily as 'safety nets' for vulnerable populations and are funded by a variety of sources, including the federal government, state governments and private foundations, as well as reimbursements from patients, based upon a sliding scale" (Livingston, 2009). Analogue participants in Study 3 mentioned the clinic they use for health care, saying that clinic gives them a "discount."

The topic of "ObamaCare" was discussed in this research phase and Study 2. A Study 3 analogue participant correctly noted that the Affordable Care Act, which they referred to as ObamaCare, requires individuals to have health insurance. However, they also said health insurance is too expansive, so they won't be able to purchase the insurance. Ortega, Rodriquez, and Bustamante (2015) note that Latinos are "likely to be disproportionately affected by the Affordable Care Act (ACA) of 2010" (p. 525). They further note that a full understanding of the ACA's impact on Latinos, both documented and undocumented, is crucial for future policy creation. Documented Latinos are eligible for Medicaid or subsidized premiums. Solutions to improve access to healthcare for the undocumented are needed to reduce health disparities.

Diabetes: What is understood. The simulated consent conference generated many questions about diabetes generally. These questions were presented in Table 17. Questions about Diabetes in Chapter 5 Results. The table is also provided below:

Table 17. Questions about Diabetes

What are the diabetic symptoms?
Do people with cholesterol issues result with diabetes?
What is diabetes Type 2?
So is it true their eyesight is affected once they start on insulin?
So, once they start using insulin, is it true that they go blind?
So it, diabetes, can show up in different ways?
I want to know the right levels [blood sugar levels] when you have diabetes and when you don't have diabetes.
How is that, that people have different levels?
What causes diabetes?
How many different types of diabetes are there?
Like insulin, for example. There are people who have to get insulin injections, right?
So how true is it that it's more likely to happen when someone is overweight?
Then the skinny ones don't get it?
Does that [insulin and pills] affect any organ in the body like the liver or kidneys?
Can upsets and frights provoke diabetes?
But I would like to know what the symptoms are?
When does someone start feeling diabetes or something like it, just to be aware?
But is there a way to control it [diabetes] without medication or not?
I want to know what are the symptoms that you are talking about with respect to the heart.
When a person is a diabetic, so like they have the need to inject insulin, what is the benefit or damage from insulin injections?
But that [stroke] happens to the person when their sugar levels are too high?

Within the contextual framework, I place these questions within the category of Community Health. The questions revolve around the etiology of the disease, the

definition, the symptoms, the treatment(s), and the results of the treatment(s). The discussion on the topic was energetic, demonstrating clear concern about the condition from many analogue participants,

> We want to ensure we can live, right?

Some analogue participants who were under a doctor's care for diabetes participated in the discussion by providing helpful explanations on symptoms and treatments as well as the name of a nearby clinic. There were instances of conflicting beliefs on the etiology of diabetes, for example, the belief that soft drinks and sweets are the cause versus the belief that malnutrition is the cause versus the belief that experiencing a *susto* (a folk illness) is the cause. This information is important and useful for medical practitioners to better understand what this community understands, misunderstands, and wants to know about this disease that is so prevalent in the Latino population. Knowledge such as this works toward more culturally competent care, which in turn may help reduce healthcare disparities.

Several participants understood how important proper diet and exercise are in preventing and managing diabetes as well as high cholesterol and high blood pressure. Some participants said they had been diagnosed as "pre-diabetic." Some of these participants, as well as participants who were currently being treated for diabetes, were meeting with a dietician,

> They have told me to take care of myself. And that right now I have to have the services of a nutritionist so that they can observe so that I can learn how to eat right and all that. The thing of it is that I have pre-diabetes.

This data highlights the importance of addressing the findings from Study 1 of the research that showed a concern about diet within the community. The analogue participants explained that they knew their diets are unhealthy. They also explained that their children did not have enough physical activity. One reason for poor diets and lack

of activity was the time both parents spent working as well as lack of knowledge of a proper diet.

Unconventional treatments, compliance. There was some evidence on the use of unconventional treatments; one participant explained that she takes pills that are sent to her from Ecuador along with using some creams for constant pain,

> It [pill] makes me feel better, along with some creams, and then I can work. I can work and work and work with only the aid of the cream and that pill.

Another person described an instance of non-compliance. She had been prescribed medication for diabetes and for high cholesterol along with instructions to take vitamins. She said the cholesterol medication hurt her stomach so she stopped taking it along with the vitamins. She now eats oatmeal and an apple daily to control her cholesterol.

The influence of family encouraging and supporting family members in managing their diabetes was also illustrated. An analogue participant, a mother, described sharing the results of her doctor's appointment with her children,

> So that's what I told my children, since I tell them everything.

She then recounted her daughter's angry reaction to this news, with her daughter reminding her that her children work so she doesn't have to, have signed her up for the gym, of which she doesn't go, and have asked her to, at the very least, go outside and walk, which she won't do. The diabetic mother then resolved to be more compliant,

> From that week, I made a commitment so that when they rechecked me it went down, down, down, to 150, 120, a hundred like that…with that, little by little, I was able to reduce it without taking insulin.

Folk illness. The first evidence of folk illness was found in this research phase. The narrative below was presented in the Results section, and I have provided it again here. This story is a narrative of one woman's journey with diabetes including its etiology (susto), issues of noncompliance, symptoms, and treatments,

> Yes. See, I am from El Salvador but I lived in Mexico. Since I worked in the evenings, I was assaulted. It made me very scared so I was in a state of shock (*me asusté*). So then a woman gave me two big, like this, glasses of water to drink. It's a remedy for a fright (*el susto*). But that's the worst thing that people can do when they have a fright (*un susto*). Then in the nineties, from there I came to the U.S. They told me that I was pre-diabetic and gave me some medicine. I thought this doctor was crazy, since I never…don't even come from a diabetic family. So then I was considering what the fright (*susto*) had to do with it. But since I didn't take the medicine, I decided to just leave it and started working at a fabric warehouse. I wanted to lose weight by wrapping myself with plastic, because I was big, not very big, but somewhat big. So then I started losing weight and more weight. And a co-worked asked me what I was doing since I had lost a lot of weight. And I told her that I didn't know. From there she took me to the doctor. My sugar reading was at 500. Super high that the doctor got shocked (*se asustó*). They had asked what had happened and I told them that I didn't know. I had an uncontrollable thirst that I would buy Coke and drink, and drink. I would also not even sleep because I would spend most of the time in the bathroom. And the doctor told me they are going to give me an insulin injection and that I was going to feel better. It was insulin that was able to control it for me. But during that same time, I had had a very big problem with my husband that I drank water again and that was bad [referring to the fact that drinking water for a *susto* is ill advised]. So then most recently, could be because of the weather or because I work a lot, my knees started hurting. So they gave me cortisone injections and cortisone raises the blood sugar. So I could only have insulin. Right now

> I am taking insulin. It is 8 units of insulin every 24 hours due to the fact that I cannot control it with pills. So then I am going every Wednesday to a meeting for diabetics at, it's a clinic. They are showing us what to eat there. So now, like how is it, I have lost weight because I no longer eat greasy foods and now I eat more vegetables. And that helped lower my cholesterol. But it is so close. So like right now, I live in St. Paul. I have a problem with my baby sister that I get a severe headache that it hurts right here and even my mouth gets all dry. So then my sister says to me like she is a believer in the churchy things. She says do what the prophet so and so says if you see the bad, then you should flee from it. So if you see that is what is affecting you most, then that's what she says. My husband is right now in the state of Washington so right now I don't have that problem. You know, he drinks and all that. We would also fight like cats and dogs. It was the same story. But in that regard, I am at peace now. After living with my niece, I decided to move back to Minneapolis and try to control my sugar. Right now I am having to take 8 units. For now, I have been waking with sugar reading of 90, 105, it has not gotten any higher. But last time we had problems, it was in the 200s. So it's my opinion that frights (*sustos de corajes*) and things like that are the cause of it [diabetes].

Susto, meaning fright, is folk illness common in Mexico and Latin America. Weller et al. (2002) explains "*susto* is considered to be a potentially dangerous condition by the majority of those we interviewed. Respondents in Mexico and Guatemala felt that people could die, develop diabetes or have their blood turn to water as a result of *susto*" (p. 469). Scholars have reported that symptoms and treatments of this illness varies across populations. For example, in indigenous populations the results of *susto* center on the loss of the soul or the vital substance. The treatment may include a ritual involving sweeping the body with herbs while saying prayers. The branch of herbs that is used is called a *barrida*.

In general, "Symptoms may include malaise, difficulty sleeping, poor appetite, and sometimes gastro-intestinal complaints (stomach ache, diarrhea, vomiting)" (Weller et al., 2002, p. 449-450). Weller et al. (2002) report on a study done by Trotter (1982) in South Texas. Among those interviewed, two-thirds reported treating *susto* with teas or water with sugar, vinegar, or salt. One-third of those interviewed report using a *barrida*.

The analogue participant in this study is describing having a *susto* and being given two large glasses of water to drink. Later she describes a problem with her husband, who we assume abused alcohol, and says she once again drank water. She believes that these *sustos* are the cause of her diabetes. This correlation between drinking water after a *susto* and diabetes is mentioned in a study that examined *susto* and soul loss in Mexicans and Mexican Americans by Glazer, Baer, Weller, Alba, and Liebowitz (2004). They found that in participants from Guadalajara, "some (12%) suggested refraining from drinking anything but eating a piece of French roll (*pan birote*) [after experiencing a *susto*]. The latter treatment was said to be important to prevent diabetes (and/or *bilis*) from occurring as a result of the *susto*" (p. 277).

When she was first diagnosed as pre-diabetic this analogue participant did not take the medication she was given because she did not believe she was pre-diabetic since she had no family history. Her co-worker took her to a doctor when she started losing weight and she was diagnosed with diabetes. During that time she was having problems with her husband and presumably experienced another *susto* followed by drinking water. At the end of her story she describes her current medical treatment. She mentions her sister advised her based on her sister's faith.

Faith was evident in another story told by an analogue participant. As exhibited in the Results section, the participant described a person they knew who had kidney problems, but since that person was undocumented "they" would not operate on him,

> Thanks to God, it appears that God has healed him that he no longer needs the operation.

Related to the role of faith in illness is the cultural value of *fatalismo* (fatalism), a belief that an individual has little control to alter fate. Flores (2000), exploring cultural competency in healthcare writes, "*Fatalismo* can result in important adverse health consequences, including less preventive screening and avoidance of effective therapy for cancer and chronic diseases" (p. 16). This cultural value is reflected in the *dicho* (common saying), *Si Dios quiere* (if God wills).

Presenting information. Current properties were strengthened within the category Presenting Information, such as a need to clarify the concept of randomization and a need to use "more simple language." The participants asked that the consent conference clearly state whether undocumented people can participate and whether potential participants were required to have health insurance. With respect to the diabetes trial used as the simulated conference, the analogue participants requested clearer information on the genetic component of this study since some analogue participants felt there was a potential conflict with the genetic study and their religious beliefs.

I refer the reader to Chapter 3 p. 114 to review the effect the social context reflected in the conceptual framework, Fig. 4, has on the community members' ability to exercise their autonomy. The content of that discussion is unaffected by the Study 3 data, though the composition of the social context is enriched.

If this conference trial were being presented to potential participants with similar demographics as this population, with no change in the current materials it would be difficult to promote autonomy. I refer the reader to Chapter 3 Discussion, subsection "Presenting information" (p.114) for advice on how the ACCORD conference and consent form may be revised for use in this community.

Understanding. It is interesting that there was no conversation on the complexity of the consent form. The Flesch-Kincaid Grade Level of the form is 13.1, which far exceeds the education level of the participants. It is 16 pages long and, in my opinion, exhibits extremely poor document design elements. The analogue participants actually

paid little attention to the form, choosing to listen to the consent script, which also had a Flesch-Kincaid Grade Level of 13.1. Attempting to understand the presented information, the participants asked questions and contextualized by engaging in personal narratives. However, there is no guarantee that a consent form requiring a lower reading level would be comprehensible to the analogue participant. Cortes, Drainoni, Henault, and Paasche-Orlow (2010) report on a study by Davis and colleagues (2002) testing "a simplified, illustrated consent document that followed low literacy recommendations" on participants with "marginal-to-low reading skills" (p. 178). The researchers found no difference in comprehension between this form and the standard version. This suggests that the process of comprehension of consent information is much more complex than modifying the textual consent form. In a study by Sudore et al. (2006), "minority status was independently associated with poor comprehension and requiring more passes through the consent process, suggesting that other factors, such as mistrust or racial/ethnic discordance between interviewer and subject may contribute to poor understanding" (p. 871). In this study, I see the participants' social context as being a prevailing factor. While trust and racial concordance may play a factor, educational level, socioeconomic status, and immigration status are also factors.

With respect to the Burkeian notion of Identification (see p. 144, "A rhetorical account)", the participants were reacting to the topic of the trial. The analogue participants in Study 1 and Study 2 perceived that the researchers were intending to help them. The participants identified with the researchers because the topics of the study used in the simulation were topics that held deep importance for them: their children, their diets, and their health. The analogue participants in this research phase did not seem to feel that the researchers were intending to help them, though they similarly were identifying with the topic of the trial. The topic, diabetes, represents a prevailing health concern within their community, directly affecting many of the participants. The analogue participants were looking for medical knowledge and treatment and many said they would participate in the ACCORD trial if they were actually being recruited,

however, they felt that, since they were undocumented, they would not be given the opportunity.

Trial design: Justice. There was data in this research study that spoke directly to the third ethical principle of the *Belmont Report* (1979), justice. This principle involves issues regarding who is receiving the benefits of research and who is bearing the burdens. One analogue participant asked,

> The issue, is this study for the benefit of the medical community? Or is it a benefit for the community itself? Why? Because we are paying. If we participate, then we are paying for the study because you would be charging us, right? So the main idea is for us to help in the study?

Another participant said she would not participate because it was,

> Like the bunnies from India, right? It would be that.

When asked what that phrase meant she said,

> They use you like rats for inventions.

In other words, the researchers would be using her as a guinea pig, taking advantage of her. Related to issues of inclusion, two analogue participants noted,

> Of course they will probably would not accept us because we do not have documentation.

> But because of no documentation they do not want to perform a surgery on an individual. Just imagine, since we don't have documentation, will they even want us involved in this [the trial]?

It should be noted that during both focus groups the analogue participants were asked to give a show of hands indicating whether they would participate in the diabetes trial represented in the simulation. More than one-third of each group indicated they

would participate if given the opportunity. Finally, though not only representing the principle of justice, but certainly a matter of ethical concern, is the potential for a conflict of interest mentioned by one participant,

> In addition, many studies that are done are for the very same companies that produce the medication.

Conflicts of interest related to clinical trials can result in serious bioethical breaches.[32] These breaches hold potential to affect all three ethic principals: autonomy, beneficence, and justice. To account for these ethical issues as well as the matters of justice evidenced in Study 2 and 3, an additional category was created, Trial Design. Trial Design is directly associated with the category Presenting Information as shown in the conceptual framework, Fig. 14. The trial design needs to account for all bioethical principles. Only then can the descriptive information be created.

The following conceptual framework highlights the the effects of Study 3 data. The next chapter considers the results of all three studies and present the grounded theory.

[32] To read an overview of the issue I suggest the introduction to the special issue of the American Journal of Bioethics Summer 2002, Carrol, K. A., McGee, G. (2002). Conflict of interest in AJOB. *American Journal of Bioethics. 2*(3). pp. 1–2.

Chapter 6: The Grounded Theory:
Informed Consent as a Form of Technical Communication

Del dicho al hecho, hay mucho trecho

From the word to the deed there is a great distance

This chapter presents the grounded theory resulting from the data gathered in Study 1, Study 2, and Study 3. The theory suggests a culturally specific way to present trial information to members of this community, describes how that information might be understood, and illustrates the community's social context. Understanding the social context is necessary to understand how to present trial information and to understand the autonomy of community members. All of this is operationalized by treating the process of informed consent as a form of Technical Communication

Table 18. English Fluency

	English Fluency* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 1	20%	10–>12	Too few to calculate 1 person: 36 years 2 people: 46 years	11–>25	Too few to calculate 1 person: 25 years 2 people: 11 years
Study 2	11%	7–>12	40	1–36	12
Study 3	24%	0–>12	50	10–24	16
Average	18%		43		16

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

Table 19. No English Language Skills

	No English Language Skills* % of total	Education (years)	Median** Age (years)	Years in U.S.	Median*** Years in the U.S.
Study 1	40%	0–9	45	<1–20	13
Study 2	53%	0–>12	50	<1–41	10
Study 3	64%	0–>12	40	11–30	14
Average	52%		45		12

* percentages of fluency do not add up to 100% due to some participants reporting amid-level English language ability

** ages were reported in ranges, e.g. 26–36; to calculate a median an approximate midpoint in the range was used

*** years in the U.S. were reported at times in ranges, e.g. 5–10, at times by an exact number of years; to calculate a median an approximate midpoint of the range was used

Across all three research phases, looking at the average values, there is no correlation between time spent in the U.S. and English language ability nor age and English language ability. The majority of the analogue participants possessed little to no English language skills. There is evidence that there was a lower level of education within this group of participants.

The final category summary appears below in Table 20. Final Category Summary. Along with the final conceptual framework, Fig. 16 the reader can view the relationships between the categories that form the grounded theory.

Table 20. Final Category Summary

Thematic Category	Datum Supporting Theme	Interpretive Summary
Community members care and concern for one another	We want an explanation for our community so everybody can have an opinion on this topic.	The category Community members care and concern for one another represent the importance of the community to its members. As well as direct comments about community and family members, the extensive use of the pronouns "we" and "us" reflects the importance of the community to its members. Close familial ties is a property of this category..
Immigration Status	We're very stressed about it. Because everything that's happened. The watchful groups, the immigration, the reform, police treatment, watchful groups…all of that affects the Hispanic community in one way or another. Even if you want to get near for a good cause, [the study] well now they're afraid and can't trust.	The category Immigration Status categorizes data related to the analogue participant's status as documented or undocumented immigrants, an overriding issue for many of the participants and one that affects the entire Latino community. Being undocumented restricts trial participation due to fears of deportation. Importantly it also impedes desired participation, contributing to health inequities.
Effects of Working	The work and money are the ambition and results in the bad things in the home…And in this country where there's a lot of work, one can leave their	The category Effects of Working categorizes data describing how work is viewed and how it affects members of this community. The data

Thematic Category	Datum Supporting Theme	Interpretive Summary
	family to come here to work to do things they shouldn't be. Also in video games, as Latinos work a lot and their kids are left with the video games, the crime. That's what happens to our people. We're rotting.	shows that the participants work many jobs and this affects the family's diet, the care of the children, and may restrict participation in a study due to time restrictions. Significantly, the traditional family structure is being disrupted, without a clear way to negotiate the new reality. The cultural value of *familismo* is threatened.
Community Health	…educate the Latino families to eat more healthy because unfortunately we are overweight, we have families with diabetes, children with diabetes, and uhm sick because they are too skinny that the children are practically anemic.	The category Community Health is closely linked with the category Effects of Working in that lack of time was considered by many analogue participants as the major factor in the poor diets and lack of physical activity of many in the community. This category, Community Health, categorizes data concerning the community's dietary habits and health concerns. Lack of regular medical care, lack of insurance, and expense of care are concerns. A subcategory, Navigating Care, include issues of health insurance, compliance, unconventional treatments, folk illnesses, the role of faith.

Thematic Category	Datum Supporting Theme	Interpretive Summary
Education	What I think is that, you know, well, I think it will be difficult to convince someone with a lack of education to participate; you'll need a different manner to recruit.	The category Education categorizes data related to issues affected by an individual's educational level. These issues are varied; and are interrelated to items within other categories. An individual's English language ability is a property of this category.
Issues of power and trust	I think Latinos; we need to see how it works to do it. We don't take those risks	The category Issues of Power and Trust categorizes data involved with concerns about confidentiality and issues of power and trust that were sparked by the consent conference. Fear of deportation is at the root of most issues within this category.
Understanding	That there is a group, you are looking for groups of people for some studies to help kids. What you're trying to do with us is that same thing for three years. And we'd receive some benefits but I think it's up to the person to decide, I think.	The category Understanding categorizes data that demonstrates an understanding of specific information presented during the study consent conference. A property of this category includes contextualizing to form meaning that is, using a familiar experience to make sense of a new experience. Phrases used to introduce experiences include "for example" and "in my case."

Thematic Category	Datum Supporting Theme	Interpretive Summary
Therapeutic Misconception	…there will more help for the Latino family to improve the lifestyle, to improve the relationship, to improve the foundation for anything in the future for the family.	The category Therapeutic misconception categorizes data that demonstrates what occurs when research participants believe or assume that their trial participation will provide them with the greatest possible therapeutic benefits, meeting their individual needs.
Not Understanding/ Misunderstanding	Sometimes a person doesn't understand, there were terms that I understood little.	The category Not Understanding/Misunderstanding categorizes data that demonstrates an analogue participant is not understanding or misunderstanding the study consent information.
Trial Design	The issue, is this study for the benefit of the medical community? Or is it a benefit for the community itself?	The category Trial Design accounts for problems associated with the principle of justice exhibited in the data as well as other ethical issues. The trial design needs to account for all bioethical principles. Only then can the descriptive information be created.
Presenting Information	You gave me the information but you didn't explain it to me.	The analogue participants offered practical advice on how to present a conference to enhance understanding for members of their community. These suggestions should be attended to as well the use of

Thematic Category	Datum Supporting Theme	Interpretive Summary
		STC writing precepts and attention to cultural values. The researchers should promote the autonomy of potential participants by approaching a conference as an educator. The conference should be approached as a process with the investment of time and a goal of individuating the amount of information presented. An important property of this category is that of Persuasion. Several analogue participants said the conference should convince or motivate them to participate. When persuasion is used in a trial conference the researcher should thoroughly understand the rhetorical situation (social context) and the cultural designation of the researcher's ethos to insure an ethical recruitment.

Final Conceptual Framework

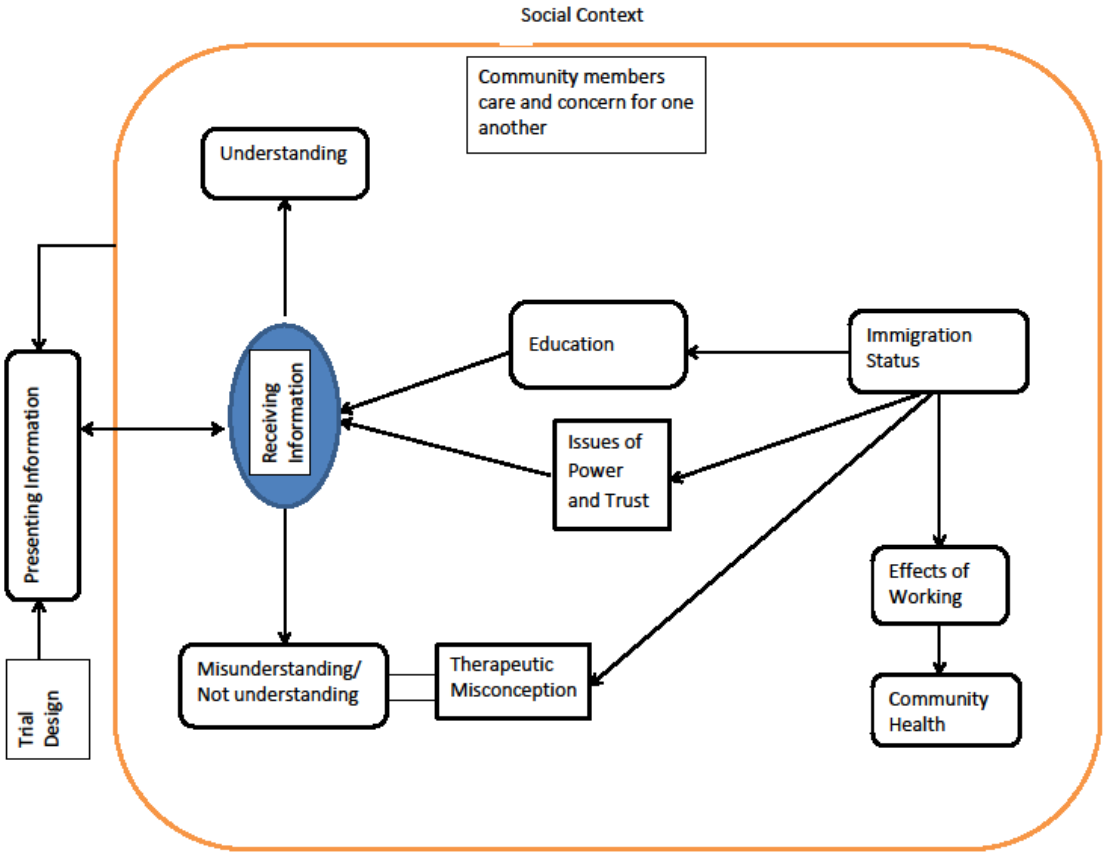

Figure 15. Final conceptual framework

In order to understand what, if any, oppressions this community faces as well as understanding the social factors that may inform an individual's decision to participate in a trial, one must understand the social context.

Social Context

The social context of this community is complex and dynamic. Latino immigrants in this study live in a closely-knit community, sharing a culture, language, faith, for the most part their country of origin, and the immigrant experience. These community members demonstrate care and concern for one another in their shared struggles to acculturate while living with a steady sense of disquietude surrounding the immigration status of themselves, family members, or friends. An undocumented status affects all areas of an immigrant's life, limiting many potential opportunities.

Many of these individuals work multiple jobs, including parents. Time spent working has resulted in poor family nutrition, a lack of physical activity, and a lack of parental supervision. The traditional family structure is disrupted and the cultural value of *familismo* is threatened by this time spent working. Community members are aware of the effects this lack of attention to their diets and their children, but do not seem to have the tools to negotiate this new reality.

A poor diet, a result of both lack of time and lack of nutritional knowledge, affects the health of many community members. Obesity is common, which contributes to many health issues, including diabetes, a disease common in this community. Many community members do not have medical insurance since affordable medical insurance is not available for undocumented people. Because of the expense, many are not able to receive healthcare on a regular basis. Some community members use natural or unconventional treatments to treat their maladies and many rely on their faith to heal. The etiology of diseases such as diabetes is rooted in folk illness for some individuals, which can complicate successful treatment.

The level of education varies within the community, though a segment of the population has little to no formal education. More significantly, 52% of this study's participants report little to no English language skills. There is no strong correlation between formal education and English language skill, though there were more individuals with low education levels in this group than the group of individuals, 18% who reported fluency in English. There was no correlation between the number of years in the U.S. and English language ability. This lack of language ability, at times coupled with low educational levels, limits employment opportunities and contributes to community isolation.

It is within this social context that community members make decisions about participating in a clinic trial.

Informed Consent Conference

Community members are interested in participating in studies that address issues that are relevant to them or their community. They look at how they or their family might benefit from participation. Monetary compensation is important for some, while an educational component is important to most. That the trial benefits as many community members as possible is also an important consideration. Anything that may expose a participant as undocumented restricts participation, such as the mandated reporter status of the researcher. Also, research involving family is often approached cautiously. Another deterrent for this community is a lack of time due to work responsibilities.

The data hinted at issues of justice. The principle of justice seeks expression in the careful consideration of who is selected to be subjected to the risks of research as well as who is included in possibly beneficial research. Some participants, demonstrating issues with trust and power, expressed concern over who might benefit from the simulated trial while others indicated that they wanted to participate in such a trial but suspected their undocumented status would prohibit participation. Protecting certain

groups of people by not including them in research may deprive them of possible benefits resulting from participation in clinical research. These could include either therapeutic benefits resulting from direct research participation, or benefits for a specific group. Mastroianni and Kahn (2001) have concluded that special protections for an individual should not be based only on that person's membership to a particular group, but by also looking closely at the research project itself. That consideration is represented in this data by the category Trial Design.

The data in this study provided insight into what and how the participants understood from the simulated conferences. Of note were techniques the participants employed to try to understand the information. When the presented information was complicated, participants tried to understand by asking questions and contextualizing to form meaning. Contextualizing was done by using a familiar experience to make sense of new information. Also of note was the prevalence of therapeutic misconception, a form of misunderstanding where the analogue participants believed or assumed that their trial participation would provide them with the greatest possible therapeutic benefits, meeting their individual needs.

Informed Consent as a Form of Technical Communication

The traditional autonomy framework, the principlist approach, focuses on the individual. Felt et al. (2009) observe that framing autonomy as an individual's informed choice is not adequate. Their study showed that persons don't always attend to the presented information but instead make decisions based on factors beyond the information such as personal experiences or perceptions. To acknowledge this I have adopted the feminist theory of *relational autonomy*, which Sherwin (1998) describes as a "relational conception of personhood that recognizes the importance of social forces in shaping each person's identity, development, and aspirations" (p. 35). This opens a space to consider how individuals understand and exercise autonomy within the process of informed consent.

The consent conference operationalizes the ethical principle of Respect for Persons and requires the researcher to provide information, facilitate comprehension, and foster voluntariness. In order to ethically consent members of minority communities, the consent process should be approached as a form of technical communication. The discipline of technical communication looks to communicate complex information in an understandable manner to a specific audience and as such, begins by determining the purpose of the document and performing an audience analysis.

This project reveals the results of an audience analysis— the social context— that informs how these community members understand the information presented in a consent conference as well the nature of their autonomy. It also gives the researcher insight into how and what information should be presented and what factors facilitate or restrict trial participation. This project nuances the audience analysis to show just how fully one might be able to understand their audience and their audience's communication needs and preferences.

The audience analysis also provides information on the audience member's autonomy. If autonomy is compromised the researcher must first determine if they can ethically participate in the trial. If it is decided that inclusion is possible, the researcher should approach informed consent as an ongoing process and one that requires an interpretation that is more complex than the traditional conception of consent. The focus should be on "the development and exercise of people's autonomy competency" (Meyers as cited in Dodds, 2000, p. 231). This includes Warren's (1989) advice that the researcher approaches a conference as an educator, not as an authority. This works to disrupt power differentials and enables understanding since the researcher is working to connect with the individual and is probing to get feedback so that confusing information can be repeated and clarified and additional information can be added. Technical Communication focuses on making the presented information assessable to its audience. This goes farther than textual documents. In the case of consent for minority

communities, the consent should be considered a process with an investment in time and a goal of individuating the amount of information presented.

Technical communication also includes the practice of document design. The participants of this study provided many practical design suggestions, all common features of technical communication, all of which should be attended to, such as:

- Communicate in a direct manner
- Focus on the main points
- Provide a strong introduction forecasting what will be covered
- Use plain language
- Read all materials aloud (to accommodate low literacy)
- Use visuals

They also provided culturally specific suggestions, such as:

- Clearly state whether "illegal" persons can participate
- Use the term "study" not "investigation"
- Keep consent form short
- Keep presentation short
- Present the information in sections and confirm comprehension with exercises after each section
- Send all information via postal mail prior to the meeting
- Conduct the consent process with a group of Latinos rather than individually
- Have a Latino who has or is participating in that or a similar trial available at the conference to answer questions and discuss their experience (testimonial)

- Have other family members and/or trusted community members involved in the conference
- Motivate the potential participants

These culturally specific suggestions cannot be adopted without considering the ethical implications of each. For example, there is literature that supports bullets 3 and 4, though the researcher must carefully weigh what information is included against what is required. Bullet 7 might be accomplished by providing trial background information to a group of Latinos, followed by individual consent conferences.

Treating the informed consent conference as a form of technical communication dictates that an audience analysis be preformed prior to creating consent materials. This provides the information needed to tailor the cosent conference to best meet the ethical and communication needs of the potententail participants. This is particularly necessary when enrolling members of minority communities.

Inter-text

Advice for the researcher

Figure 16. The jewelry I was wearing when given this advice

So yeah, I mean, yeah, I think people will talk but it because depends on the attitude of the interviewer is how you can (can't hear) especially ahh if its someone that, that ahh who looks like us you know? (researcher: affirmative sound) that is not dressed so fancy (researcher: affirmative sound) that looks like me (researcher; that you can sit down and talk to) I see someone with rings all that stuff and I feel intimidated and I know others will feel intimidated, well not me, I won't.

Chapter 7: Implications, Research Qualilty, Limitations, Future Research

No hay mal que por bien no venga

There is no bad that good does not accompany

Introduction

This chapter begins with the significance and implications of the grounded theory resulting from this research. The quality of this research is then addressed from a broad epistemological position, identifying strengths and limitation within each criterion. Further limitations are then identified and discussed. Finally, future research topics are explored.

Implications

This grounded theory is a humanities contribution to the field of bioethics. It challenges the efficacy of the standard informed consent process for members of the immigrant Latino community and provides insights into difficulties understanding presented information. This information then suggests approaches to enroll community members into a clinical trial morally. By "morally," I mean using techniques that communicate as effectively as possible with this particular population, acknowledging the efficacy varies by individual. The grounded theory provides practical, cultural, and theoretical approaches for the consent process.

Table 13. displays the pragmatic communication advice provided by study participants on how best to communicate with the Latino community. The data also highlights the overwhelming importance of understanding the impact the social context has on individual autonomy. The researcher should develop an individual's autonomy by approaching a conference as an educator, not as an authority. This works to disrupt power differentials and works toward enabling understanding since the researcher is working to connect with the individual and is probing to get feedback so confusing information can be repeated and clarified. The conference should be considered a

process, with an investment in time and a goal of individuating the amount of information presented.

The grounded theory also demonstrates the usefulness of rhetorical analysis in explicating phenomena. The Burkeian (1969, 1966) concepts of identification and terministic screens provide an analysis of what elements of the consent process resonate with these participants as well as supplying a plausible explanation of the existence of therapeutic misconceptions. Additionally, understanding that some participants were asking for a persuasive element in the consent information, the researcher can take proper care in employing only ethical persuasion, honoring autonomy.

Finally, this theory works toward reducing health disparities is a number of ways. First, the justice issues regarding inclusion highlight the need to promote trials that include immigrant Latinos, working to better generalize trial results, especially for public health issues and diseases disproportionately evident in this community. Second, insights into how community members struggle with maintaining a healthy diet and taking exercise is useful to public health providers. And third, insights into how some community members understand the etiology and treatment of diabetes are useful to medical providers in order to most effectively educate and treat this population.

Research Quality

Currently there is not agreement among qualitative research scholars on how best to judge the quality of qualitative research. For example, Charmaz (2006) suggests reflecting on the following criteria: credibility, originality, resonance, and usefulness. I am adapting the criteria suggested by Miles, Huberman, and Saldaña (2014) because this approach is situated "broadly in the critical realist tradition" (p. 311). Addressing quality from a broad epistemological position will, I believe, establish credibility as comprehensively as possible. This criteria includes objectivity/confirmability, reliability/dependability/auditability, internal validity/credibility/authenticity, external validity/transferability/fittingness, and utilization/application/action orientation.

Traditional quality terms are paired with terms that more closely apply to qualitative research.

Objectivity/confirmability. From a traditional research perspective, objectivity examines the researcher's bias. In an objectivist grounded theory approach the researcher is a neutral observer who treats the relationship with the participants as unproblematic. I have adopted the method of grounded theory described by Charmaz (2006), who incorporates a symbolic interactionist theoretical perspective, which directs us to "construct our grounded theories through our past and present involvements and interactions with people, perspectives, and research practices" (p. 10). The data are co-constructed by the researcher and the participants; it is not simply observed phenomena. According to Charmaz (2006), "The constructivist position views research as an emergent product of particular times, social conditions, and interactional situations" (p. 160). Constructivists feel the research method resides within the research process.

This approach requires that I understand and acknowledge my involvement as the researcher. Mauthner and Doucet (2003) remind us "that as researchers we need to be reflexive about, and articulate, the ontological nature of subjects and subjectivities we are using in our research as well as the epistemological assumptions underpinning our methods of data analysis and knowledge construction" (p. 416). To view my depiction of my role as the researcher in this project, see Appendix D.

Another requirement for this category is that the methodology be clearly and completely described as well as providing an explicit explanation on how the resulting data was handled. I feel this has been sufficiently addressed.

Reliability/dependability/auditability. This category of criteria looks to see how consistent the study process remained over time. To consider this, the clarity of the research questions are important as well as looking to see if the data was collected appropriately for those questions. I believe I demonstrated appropriate sampling as well as providing evolving answers to the research questions as the study progressed.

Miles, Huberman, and Saldaña (2014) also require that the "Basic paradigms and analytic constructs are clearly specified. (Reliability depends, in part, on its connectedness to theory)" (p. 312). The research questions are bioethical questions, examined from a multidisciplinary lens. The research questions are set within informed consent literature, rooted in principles from the *Belmont Report* (1979), and theorized by a variety of bioethicists, such as Beauchamp and Childress (2009). To examine these questions I looked to moral theories representing a feminist ethic, such as Walker (2009), Warren (1989), Sherwin (1998), and Dodds (2000), among others. I used rhetorical principles, specifically literary theorist Kenneth Burke (1969, 1966) to explain a certain phenomenon, therapeutic misconception, that appeared in the data. Finally, I consulted literature by intercultural communication scholars to identify and explain cultural aspects of the data, for example, Landis, Bennet, and Bennet (2004); Triandis et al. (1984); Gudykunst and Kim (2003); and Elder et al. (2009).

A limitation of this study that falls within this category is the lack of intercoder reliability checks. I did not have additional researchers working on this study with me. However, I did check codes periodically with the interpreter/translator since she had been present during all data collection. I also checked some of my interpretations with the community church leaders. The use of intercoder reliability checks would have strengthened the results of this study.

Internal validity/credibility/authenticity. Babbie (2007) defines internal validity as "the possibility that the conclusions drawn from experimental results may not accurately reflect what has gone on in the experiment itself" (p. 230). Though he is writing about social research, he is talking about experimental research undertaken with positivist approaches. To address this grounded theory research, Charmaz's (2006) suggestions on how to think about credibility are useful.

Responding to these suggestions, I maintain that the data generated is sufficient to merit the claims I have made, though some categories are more saturated than others.

The links between categories are logical and grounded in the data. Though I searched for instances of negative evidence, there were no clear instances found within the data.

A limitation of this study that falls within this category is that I did not return to the community to ask the participants whether they felt my conclusions were accurate (this is sometimes referred to as respondent validation). However, I did ask one of the church leaders his opinion of a preliminary version of the theory. He found the results credible and in fact added programming to the community calendar to reflect the identified needs.

External validity/transferability/fittingness. Campbell and Stanley (1963), speaking about experimental and quasi-experimental research designs say, "External validity asks the question of generalizability: To what populations, settings, treatment variables, and measurement variables can this effect be generalized" (p. 5). Bazeley (2013) notes that qualitative studies don't normally achieve the required degree of precision to claim generalizability. They say, "qualitative researchers have focused on theoretical or analytic generalization, with the goal of developing theory with application beyond the immediate context" (p. 410).

To think through this category, I use the considerations provided by Miles, Huberman, and Saldaña (2014). I am claiming the characteristics of the participants, their setting, and the analytical processes I used are sufficiently described to enable comparisons. I have also provided "thick description" so that other researchers can determine whether there is transferability to their projects. Aspects of the grounded theory are confirmed in literature, for example the participants' perceptions of the benefits of trial participation were also found by Lakes et al. (2012). However, trial enrollment of members of the immigrant Latino community is understudied, therefore the literature is scarce.

While the research approach has potential for transferability, details within the results are grounded in historical context and as such changes, for example, to immigration policy may alter participant's viewpoints.

Utilization/application/action orientation. The definition of this category provided by Miles, Huberman, and Saldaña (2014) refers mostly to community based participatory research projects (CBPR). My project was located in the community, but does not meet the standards for CBPR, which will be discussed further in the subsection titled "Future research." Therefore, I will use Charmaz's (2006) criteria on "Usefulness" to discuss my project within this category.

The results of this research project offer researchers practical advice on how to best, or morally, enroll members of this community into clinical trials. An important part of this advice is the prescription for researchers to examine potential participants' social context in order to assess their autonomy. Adjustments to the enrollment conference should be made to accommodate and address compromised autonomy. This result is transferable.

A detailed examination of the significance and implications of this project are provided in the first subsection of this chapter.

Limitations

There are several limitations in this research project. Two limitations have been identified in the preceding subsection, I did not employ intercoder reliability checks and I did not return to the community to solicit opinions on the accuracy of the resultant theory. Two additional limitations are claims on category saturation and possible problems introduced by translations.

Charmaz (2006) defines category saturation this way, "categories are 'saturated' when gathering fresh data no longer sparks new theoretical insights, nor reveals new properties of these core theoretical categories" (p. 113). As mentioned, the Study 3 focus

groups were constrained to one hour. Due to the complexity of that trial consent, I was unable to get through all the materials in the allotted time. The participant's reactions to the complete consent materials could further develop the properties of the sub-category Navigating Care (a subcategory of Community Health) as well as develop the new category Trial Design. Because of this situation, I feel I can only make partial claims on category saturation.

Translation. This project involved extensive translation including the following documents:

- This project's consent materials
- Interview questions
- Interview procedure
- Demographic Questionnaire
- Launch scripts (3)
- Flyer contents (3)
- Diabetes Trial Consent Form
- Diabetes Trial consent script
- Interview and focus group transcriptions (21)

Temple and Young (2004) say one of the first points to establish in a situation where translation is involved is the epistemological position of the researcher. There are those who consider themselves as objective instruments of research. If this is the stance, the translator and translation are essentially irrelevant and validity is based on correct "interpretations, register, ethics, matching of social characteristics, and neutral stances" (p. 163). However, if the researcher is taking a social constructionist position, as I am, then there is no neutral position, the translator is part of knowledge production.

In this project, the interview and focus group data was transcribed word for word and then translated. I am in a rather unusual position in that I can read Spanish and I am proficient in the spoken language, but not completely fluent, especially with colloquial

Spanish. During all interviews and focus groups, Elizabeth Nelson joined me (see Appendix F for her biography). She also did all transcriptions and translations for Study 1 and Study 3. I spot checked all transcriptions by listening to the original recordings and spot checked translations. Study 2 data was transcribed and translated by Victor Camacho who was recommended by a Mexican family friend (see Appendix F for his biography). I used this second individual due to time constraints on both myself and Elizabeth. I spot checked the transcriptions again by listening to the original recordings. I did make some changes to the translations.

Lopez, Figuero, Connor, and Maliski (2008) studied translation barriers encountered when conducting qualitative research with Spanish speakers. They point out that there are no set standards for translation in cross-cultural qualitative research. One well-known translation method is Brislin's (1970, 1980) seven principles, which are often used to translate survey instruments into languages other than their source language. Lopez et al. (2008) adapted this model to create a process for translating cross-cultural qualitative research (see Appendix Y).

Following a model such as this increases the reliability and validity of the translation. Due to time and expense restrictions, I was unable to follow these best practices: conduct back translations, have more than one translator look at each document, or pilot test translated materials. Follow the following advice from Lopez et al. (2008) would have strengthened the process: "Once transcripts were translated into the target language, analysts conducted line-by-line coding. To ensure the reliability and validity of the data, a bilingual independent analyst conducted line-by-line coding of six of the Spanish transcripts" (p. 1734). This would have provided a form of intercoder reliability checks as well as checking the quality of the translation.

Future Research

As an interdisciplinary project, there are a number of directions future research might take. It would be logical to return to these community populations to complete the

investigation of the diabetes consent materials and conduct theoretical sampling if necessary. The resulting complete theory should then be brought back to the community for comment.

Creating a consent conference or adapting an existing consent process that incorporates all that has been learned in this study and testing it for efficacy would add credibility to the grounded theory.

To further enrich this theory I also suggest conducting studies with immigrant Latinos living in rural areas. I hypothesize that the urban populations that participated in this study may have the advantage of receiving community-based health education, which might not be available to those in rural areas, affecting both understanding and autonomy.

Using principles learned in this study, I would also like to create a computer-based instruction program to test the use of that mode of disclosing trial information. A computer-based instruction program would also provide a vehicle to include short, culturally tailored quizzes after sections of information to explore comprehension. This could be done using videos and visuals to attend to issues with illiteracy.

A logical extension of this original study is to conduct further research using a Community Based Participatory Research approach (CBPR). "CBPR is a partnership approach to research that equitably involves all participants in all aspects of the research process where each person shares his/her expertise in order to enhance knowledge and develop interventions that will benefit the whole community." (Israel et al., 1998, p. 184).

Finally, ancillary topics outside of trial enrollment involving this community suggest inquiry into the evolution of the immigrant nuclear family, which might include the effects of children's acculturation on their behavior towards their parents. Also of interest is the lack of English language ability in the immigrants, even those who had been in the U.S. for several decades.

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Appendix A The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.

   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rest upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or

other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve a subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be make and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

http://www.hhs.gov/ohrp/archive/nurcode.html

Appendix B

The Belmont Report

ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
April 18, 1979

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfillingthis part of its charge, is available as

DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy.

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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ETHICAL PRINCIPLES & GUIDELINES FOR RESEARCH INVOLVING HUMAN SUBJECTS

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes(1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of

generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

PART A: BOUNDARIES BETWEEN PRACTICE & RESEARCH

A. BOUNDARIES BETWEEN PRACTICE AND RESEARCH

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergoreview for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. (2) By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project. (3)

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

PART B: BASIC ETHICAL PRINCIPLES

B. BASIC ETHICAL PRINCIPLES

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse

consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment ."Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the

reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children—even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the

earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

PART C: APPLICATIONS

C. APPLICATIONS

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited—for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also,

inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitle.

2. Assessment of Risks and Benefits. The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject—or, in

some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. ust as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly

related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

(2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

Appendix C

Invitation to Grounded Theory

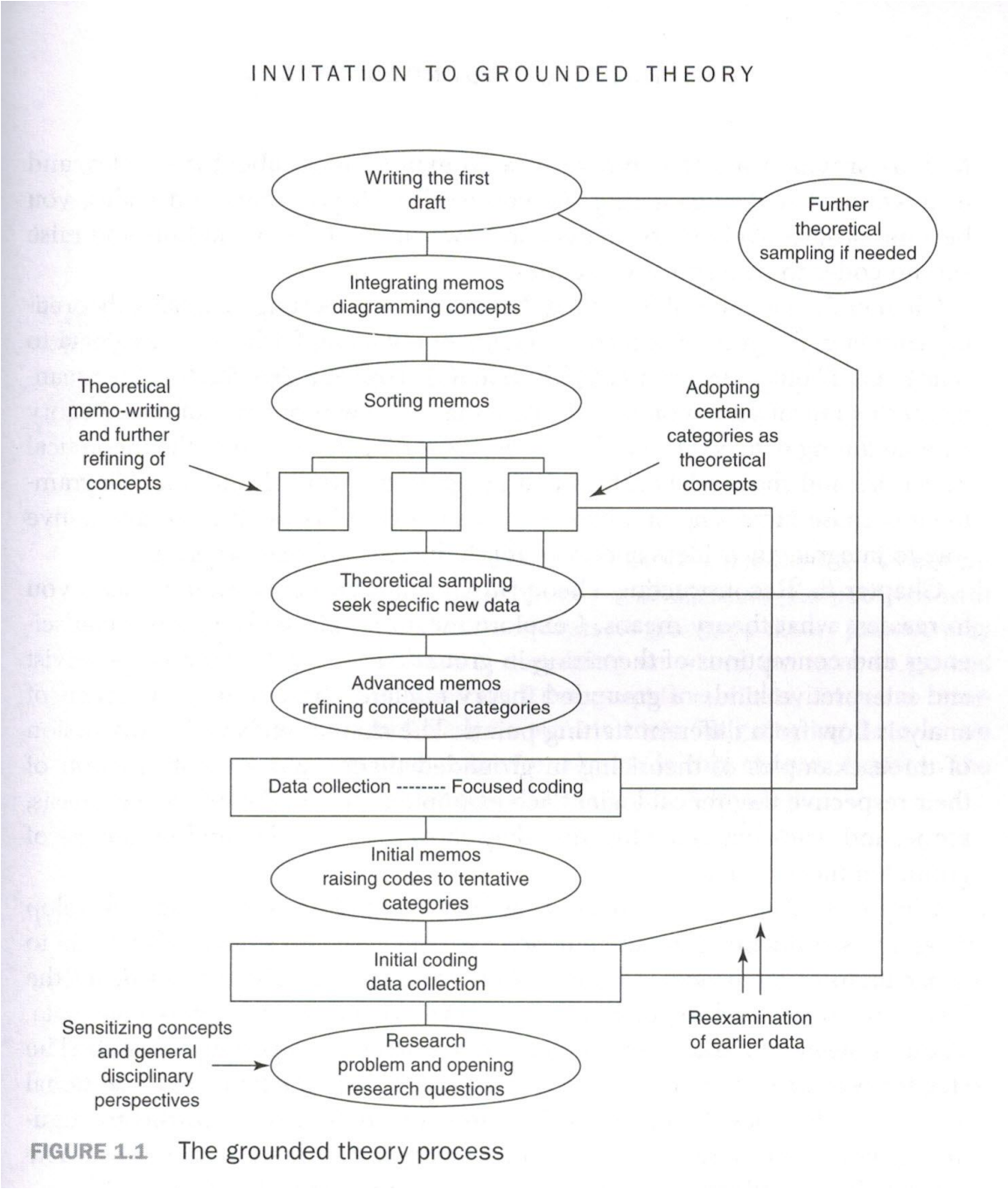


FIGURE 1.1 The grounded theory process

Appendix D

Positioning Myself in the Research

Explaining my role in the research process and the subsequent theory involves a process known as reflexivity. Charmaz (2006) defines this as,

> The researcher's scrutiny of his or her research experience, decisions, and interpretations in ways that bring the researcher into the process and allow the reader to assess how and to what extent the researcher's interests, positions, and assumptions influenced inquiry. A reflexive stance informs how the researcher conducts his or her research participants, and represents them in written reports (p. 188).

Reflexivity has not always been part of grounded theory and was not considered in the seminal works; however Strauss (1987) recognized "researchers' biographies exert influence on the use of essential grounded theory methods and the need for this to be accounted for during the research process" (Birk & Mills, 2011, p. 53). The relevance of analytic reflexivity is the subject of debate in grounded theory and in qualitative research. I will not describe this debate in detail here.[33]

The following two scholars provide an example of different sides of the debate. Haggerty (2003) describes those who use reflexivity, "reflexivists assume that in the absence of self-conscious critique that positions the author in relation to the text, readers will tend to assume that the knowledge stands above the subjectivity of the author. Consequently, self-reflexivity becomes a strategy to avoid pretensions to objectivity (p. 160). Linda Alcoff (1991) challenges the practice of a researcher speaking for others, "the practice of speaking for others is often born of a desire for mastery, to privilege oneself as the one who more correctly understands the truth about another's situation or as one can champion a just cause and thus achieve glory and praise" (p. 29). The goal in the grounded theory approach I am using is to co-create knowledge with the participants. The post-modern approach to reflexivity is a critical one.

In grounded theory reflexivity is often reflected in memos where the researcher may describe, for example, what in their background influenced how they approached

[33] For an overview see:
Haggerty, K. D. (2003). Review essay: Ruminations on reflexivity. *Current Sociology, 51*(2), 153-162.

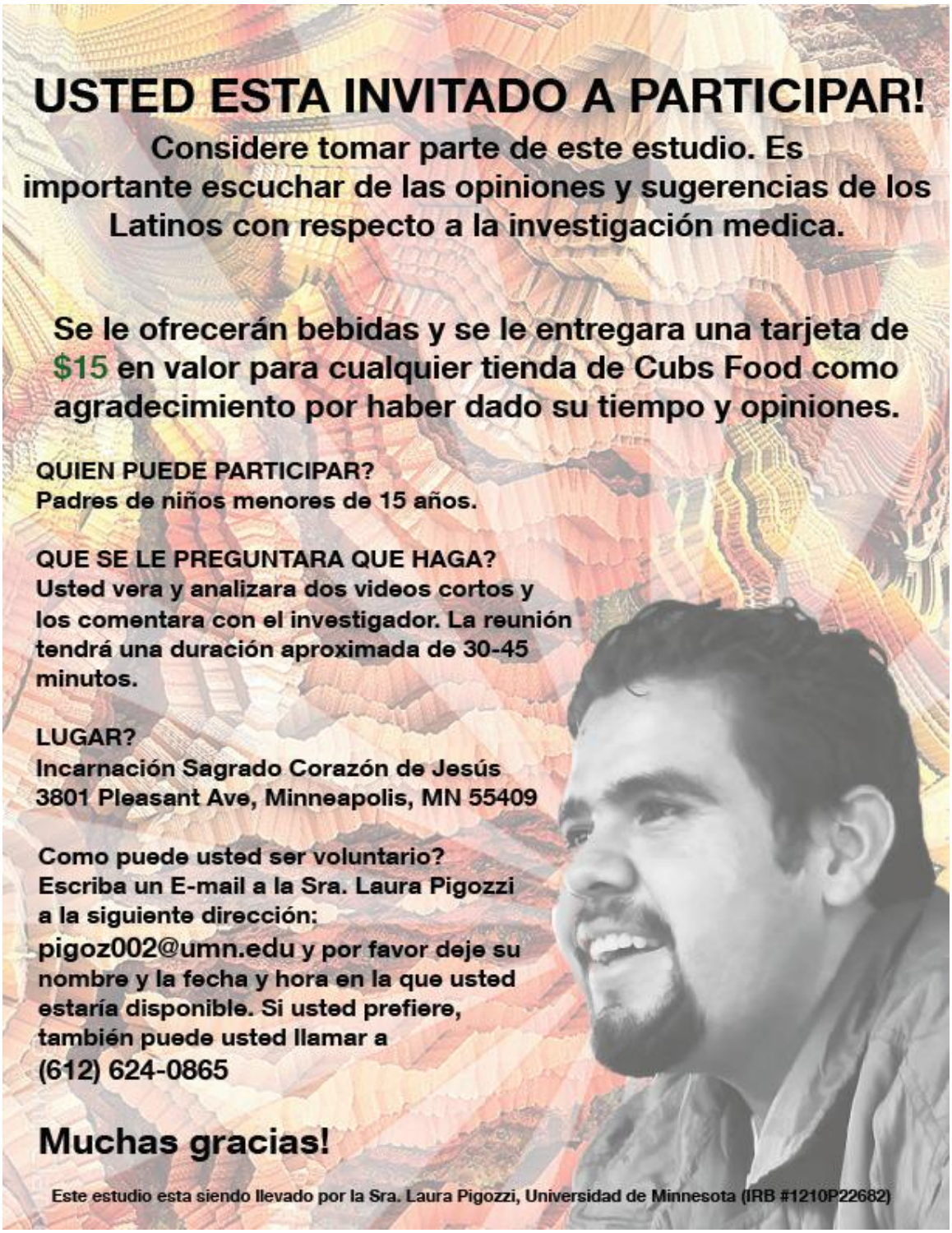
participants during an interview. Reflexivity is reflected in some of my memos, though I did not write specific "Reflexive Memos". Since the reader does not have access to these memos, I will provide a brief description of the vantage points my history has created as well as my understanding of the power differences at work in this project.

My mother is first generation Mexican-American and my father is 3rd generation Irish-American. My Mexican grandmother, who spoke only Spanish, my mother's sisters and brother, and their families all lived in the town I grew up in. As a child I spent a lot of time with them, especially my aunts. I was spoken to in Spanish by my grandmother, though I answered in English. Because of this background I am comfortable in the communities where I conduct research and understand the customs and the expectations. The danger of this comfort level is that I need to mindful of making assumptions such as providing motives for the participant's thoughts rather than listening to their voices. My father is an engineer as am I. This positivist training made grounded theory a challenge. For example, I had to re-code the initial data three times before I was not imposing existing frameworks. Life experiences such as careers prior to entering into the PhD program, parenthood, and community involvement also create vantage points.

There are many power differentials at work in this project. Though I provide a degree of racial-concordance, I am American born, educated, and represent a powerful institution. I am also older than many of the participants, which culturally, requires the participants to give me a measure of respect. For these reasons, participants may agree with me simply as a matter of politeness. Elizabeth (the interpreter) and I consciously worked to keep these issues in mind and for the most part I think we succeeded. The interview conversations were candid and relaxed.

Appendix E

Flyer Invitation Spanish



Appendix E

Flyer Invitation English translation

You are invited to participate!

Consider taking part in this study. It is important to hear the views and suggestions of Latinos with regard to medical research.

You will be offered refreshments and a card worth $15 for use at any Cub Foods store as appreciation for giving your time and opinions.

Who can participate?
Parents of children under 15 year of ages.

What will you be asked to do?

You will watch and analyze two short videos and comment on them with the investigator. The meeting will last approximately 30 -45 minutes.

Location?
Incarnanción Sagrado Corazón de Jesús
3801 Pleasant Ave, Minneapolis, MN 55409

How can you become a volunteer?

Write an email to Ms. Laura Pigozzi at the following address:
pigoz002@umn.edu and please leave your name and the date and time you will be available.

If you prefer, you may also call 612.624.0865.

Thank you!

Appendix F

Biographies

Elizabeth Nelson Interpreter, Transcriber, Translator

Ms. Nelson, who is a native Texan from humble beginnings, received a Master's of Education (M. Ed.) in Human Resource Development and a minor in leadership from the University of Minnesota; she also holds a B.A. in Chicano Studies from the University of Minnesota. She lives in the Twin Cities area and has three teenagers. Elizabeth Nelson is the Office Manager and Human Resource contact of the TRIO Upward Bound (TRIO UB), a federally sponsored college preparatory high school program in the College of Education and Human Development (CEHD). She also serves as an interpreter for the Spanish speaking participants' family and is the Event and Scholarship Coordinator for the "Minnesota I Have a Dream Scholarship" in addition to preparing the United States Education Department Annual Performance Report.

A free-lance interpreter by trade, Ms. Nelson joined the University of Minnesota in 2007. Her public service as an interpreter for professional development sessions, conferences, and research focus on issues related to access and equity, concentrating on providing the meaning of the message from English to Spanish and vice-versa across differences of ethnicity, gender, and class. Ms. Nelson is an affiliate and member of the National Association of Professional Women (NAPW) and Continental Who's Who, and International Women's Leadership Association (IWLA). She holds the NAPW 2013/2014 Woman of the Year Award, University of Minnesota Women of Color Tapestry Award 2012. She is a Ray G. Price Endowed Fellowship 2014 recipient, certified Meyers Briggs Type Indicator (MBTI) I & II practitioner, and is on the Minnesota Judicial roster of court interpreters.

Victor Camacho Transcriber,Translator

Studies: Communication Sciences -México City 1991

Languages: English, Italian, Spanish

Courses: Italian Language-Florence, Italy 2002

Work Experience: Children Hospital St. Paul MN 1996-1998 Freelance Professional Translator & Interpreter.

Hennepin County Medical Center & Hennepin County Court System Minneapolis, MN 2002, 2007 Freelance Professional Translator and Interpreter.

Appendix G

Pigozzi Informed Consent Spanish

CONSENTIMIENTO PARA PARTICIPAR EN LA INVESTIGACIÓN

Les pido que formen parte de este estudio. Estoy interesada en escuchar las opiniones y sugerencias de la comunidad Latina sobre el proceso de poder inscribir personas en las investigaciones de los estudios médicos. Investigaciones como esta será útil para poder desarrollar un procedimiento en el cual la inscripción de ls miembros de la comunidad Latina funcione mejor.

Le hare algunas preguntas demográficas (tales como su edad y país de origen) y también algunos de los términos médicos. A continuación le voy a preguntar que vea dos videos cortos, después discutiremos sus opiniones y pensamientos acerca de los videos. Les informo que yo grabare nuestra conversación, simplemente nuestra conversación, sus nombres NO SERAN utilizados y serán anónimos en sus comentarios.

Como el investigador, no veo ningún riesgo asociados con su participación en este estudio. Su identidad se mantendrá totalmente confidencial. Usted tendrá la libertad de hablar de cualquier manera que elija durante la discusión. Al mismo tiempo, usted tendrá permitido irse en cualquier momento. El beneficio de participar es su contribución al conocimiento sobre el consentimiento informado.

En agradecimiento por su tiempo y participación, le ofreceré una tarjeta de regalo de $15.00 para la tienda Cub Foods.

Los records (escritos y de audio) del estudio serán privados. En cualquier publicación no voy a incluir ninguna información que permita identificarle a usted como uno de mis los participantes. Los records de la investigación se almacenan de forma segura y sólo el investigador (yo) tendrán acceso a dichos records. Las cintas de audio las tendré transcritas (hare una copia por escrito) y después serán destruidas todas las grabaciones.

Lo más importante, la participación en este estudio es totalmente voluntaria. Su decisión de participar en este estudio, o no participar, no afectará ninguna relación actual o futura con la Universidad de Minnesota. Si usted decide participar, usted será libre de contestar las preguntas que elija, al mismo tiempo usted será libre de retirarse en cualquier momento.

Si tiene cualquier pregunta, favor de contactarme a:
Laura Pigozzi (investigador)
612.825.7860 (Ingles)
pigoz002@umn.edu (inglés y Español)
Elizabeth Nelson (interprete)
612.624.0865 (Español o Inglés)

Si usted tiene cualquier pregunta o inquietud acerca de esta investigación y quisiera hablar con alguien más en vez del investigador o interprete, por favor de contactar la Línea de Abogados Investigación D528 Mayo, 420 Delaware ST. SE, Minneapolis, Minnesota 55455; 612.625.1650 (Inglés)

IRB ha aprobado el derecho de renunciar firmas.

Los participantes recibirán una copia de esta información para mantener en sus archivos.

La investigación está controlada bajo la supervisión del Dr. Debra DeBruin, Centro de Bioética de la Universidad de Minnesota

Appendix G

Pigozzi Consent to Participate in Research English Translation

I am asking you to take part in a research study. I'm interested in hearing the opinions and suggestions of the Latino community about the process of enrolling people into medical research studies. Research such as this will be helpful in developing enrollment procedures that work well with members of the Latino community.

I will ask you some demographic questions (such as your age and country of origin) and ask you about some medical terms. Then I will ask you to watch two short videos and we will discuss your opinions and thoughts about those videos. I will audio record our discussion, but your names will not be used or connected to your comments.

As the researcher, I do not see any risks associated with taking part in this study. Your identity will be kept confidential. You are free to speak in any way you chose during our discussion. You are free to leave at any time. The benefit of participating is your contribution to the body of knowledge on informed consent.

To thank you for your time and participation, I will offer you a $15 Cub Food gift certificate and refreshments.

The records (written and audio) of this study will be kept private. In any publication, I will not include any information that will make it possible to identify you as a participant. Research records will be stored securely and only the researcher (myself) will have access to these records. I will have the audio tapes transcribed (make a written copy) and will then destroy the recordings.

Most importantly, participation in this study is voluntary. Your decision to participate in this study, or not participate, will not affect any current or future relationship with the University of Minnesota. If you decide to participate, you are free to answer whichever questions you chose and you are free to withdraw at any time.

If you have any questions, you may contact:
Laura Pigozzi (researcher)
612.825.7860 (English)
Pigoz002@umn.edu (English or Spanish)
Elizabeth Nelson (interpreter)
612.624.0865 (Spanish or English)

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher or interpreter, please contact the Research Subjects' Advocate Line, D528 May, 420 Delaware ST. Southeast, Minneapolis, Minnesota 55455; 612.625.1650 (English)

IRB has approved the right to waive signatures.

Participants will be given a copy of this information to keep for their records.

Research under the supervision of Dr. Debra DeBruin, Center for Bioethics, University of Minnesota

Appendix H

Información demográfica Español

1. Seleccione su edad:

   - ○ 18–25 años
   - ○ 26–35 años
   - ○ 36–45 años
   - ○ 46–55 años
   - ○ 56–65 años
   - ○ más de 65 años

2. Seleccione cuantos años usted ha vivido en los Estados Unidos:

   - ○ Nací aquí
   - ○ Menos de un año
   - ○ 1–3 años
   - ○ 3–5 años
   - ○ 5–10 años
   - ○ Si es más de 10 años, indique cuantos años: _____

3. ¿Cuál es su país de origen? _____

4. Marque el nivel de inglés que habla:

   1 2 3 4 5

   Nada de inglés Hablo inglés

5. Indique cuántos años de educación ha completado usted?

   - ○ No tengo educación formal
   - ○ 1–6 años
   - ○ 7–9 años
   - ○ 10–12 años
   - ○ Más de 12 años

Appendix H

Demographic Data Form English

1. Please indicate your age.

   - ☐ 18–25 years
   - ☐ 26–35 years
   - ☐ 36–45 years
   - ☐ 46–55 years
   - ☐ 56–65 years

2. Please indicate how many years you have been in the United States.

   - ☐ Natural born citizen
   - ☐ Less than 1 year
   - ☐ 1–3 years
   - ☐ 3–5 years
   - ☐ 5–10 years
   - ☐ More than 10 years. Indicate number of years: _____

3. What is your country of origin: _____

4. Please rate your proficiency in speaking English.

   1 2 3 4 5

   No English Fluent

5. Please indicate how many years of education you have completed:

   - ☐ No formal education
   - ☐ 1–6 years
   - ☐ 7–9 years
   - ☐ 10–12 years
   - ☐ More than 12 years

Appendix I SAHLSA-50

Short Assessment of Health Literacy for Spanish Adults (SAHLSA-50)

The Short Assessment of Health Literacy for Spanish Adults (SAHLSA-50) is a validated health literacy assessment tool containing 50 items designed to assess a Spanish-speaking adult's ability to read and understand common medical terms. The SAHLSA was based on the Rapid Estimates of Adult Literacy in Medicine (REALM), known as the most easily administered tool for assessing health literacy in English.

Stem	Key or Distracter		
1. próstata	glándula	circulación	no se
2. empleo	trabajo	educación	no se
3. menstrual	mensual	diario	no se
4. gripe	sano	enfermo	no se
5. avisar	medir	decir	no se
6. comidas	cena	paseo	no se
7. alcoholismo	adicción	recreo	no se
8. grasa	naranja	manteca	no se
9. asma	respirar	piel	no se
10. cafeína	energía	agua	no se
11. osteoporosis	hueso	músculo	no se
12. depresión	apetito	sentimientos	no se
13. estreñimiento	bloqueado	suelto	no se
14. embarazo	parto	niñez	no se
15. incesto	familia	vecinos	no se
16. pastilla	tableta	galleta	no se
17. testículo	óvulo	esperma	no se
18. rectal	regadera	inodoro	no se
19. ojo	oír	ver	no se
20. irritación	rígido	adolorido	no se
21. abnormal	diferente	similar	no se
22. estrés	preocupación	feliz	no se
23. aborto espontáneo	pérdida	matrimonio	no se
24. ictericia	amarillo	blanco	no se
25. papanicolaou	prueba	vacuna	no se
26. impétigo	pelo	piel	no se
27. indicado	instrucción	decisión	no se
28. ataque	herida	sano	no se
29. menopausia	señoras	niñas	no se
30. apéndice	rascar	dolor	no se
31. comportamiento	pensamiento	conducta	no se
32. nutrición	saludable	gaseosa	no se
33. diabetes	azúcar	sal	no se
34. sífilis	anticonceptivo	condón	no se
35. inflamatorio	hinchazón	sudor	no se
36. hemorroides	venas	corazón	no se
37. herpes	aire	sexo	no se
38. alérgico	resistencia	reacción	no se
39. riñón	orina	fiebre	no se
40. calorías	alimentos	vitaminas	no se

Stem	Key or Distracter		
41. medicamento	__instrumento	__tratamiento	__no se
42. anemia	__sangre	__nervio	__no se
43. intestinos	__digestión	__sudor	__no se
44. potasio	__mineral	__proteína	__no se
45. colitis	__intestino	__vejiga	__no se
46. obesidad	__peso	__altura	__no se
47. hepatitis	__pulmón	__hígado	__no se
48. vesícula biliar	__arteria	__órgano	__no se
49. convulsiones	__mareado	__tranquilo	__no se
50. artritis	__estómago	__articulación	__no se

Instructions for Administering SAHLSA-50

Administration of the test could be facilitated by using laminated 4"×5" flash cards, with each card containing a medical term printed in boldface on the top and the two association words—i.e., the key and the distracter—at the bottom.

Directions to the Interviewer:

1. Before the test, the interviewer should say to the examinee:
   "***Le voy a mostrar tarjetas con 3 palabras en ellas. Primero, me gustaría que usted lea la palabra arriba en voz alta. Entonces, yo leeré las dos palabras debajo a usted y me gustaría que usted me dijera cuál de las dos palabras es más similar a la palabra arriba. Si usted no sabe la respuesta, por favor diga, 'no se'. No adivine.***"

2. Show the examinee the first card.

3. The interviewer should say to the examinee:
   "***Ahora, por favor, lea la palabra arriba en voz alta.***"

4. The interviewer should have a clipboard with a score sheet to record the examinee's answers. The clipboard should be held such that the examinee cannot see or be distracted by the scoring procedure.

5. The interviewer will then read the key and distracter (the two words at the bottom of the card) and then say:
   "Cuál de las dos palabras es más similar a la palabra arriba? Si usted no sabe la respuesta, por favor diga, 'no se'.

6. The interviewer may repeat the instructions so that the examinee feels comfortable with the procedure.

7. Continue the test with the rest of the cards.

8. A correct answer for each test item is determined by both correct pronunciation and accurate association. Each correct answer gets one point. Once the test is completed, the interviewer should tally the total points to generate the *SAHLSA-50* score.

9. A score between 0 and 37 suggests the examinee has inadequate health literacy.

Appendix J

Priming Video

Note: Video uploaded separately.

Appendix K

Consent Conference Video

Note: Video uploaded separately.

Appendix L

NET-Works Trial Invitation Letter (Cederberg) Spanish

HealthPartners®
Research Foundation

8170 33rd Avenue South Mail Stop: 21111R
P.O. Box 1524
Minneapolis, MN 55440-1524
www.hprf.org

<Fecha>

Estimado Padre o Tutor Legal de_____:

Nuestra clínica e investigadores de la Universidad de Minnesota están trabajando juntos en una investigación de estudio llamado *NET-Works: Ahora todos Juntos para Niños mas Sanos e Increíbles*. Estamos invitando a su familia a participar porque su hijo(a) esta entre las edades de 2 a 4 y le he consultado en visitas en el pasado o tiene la proxima visita anual conmigo.

El *estudio NET-Works* ayuda a las familias de Minnesota con niños pequeños a desarrollar las prácticas positivas de crianza para el crecimiento sano del niño y la preparación escolar.

Si se inscribe, usted:

- Recibirá consejos de su proveedor acerca de las maneras de ayudar a su hijo a ser saludable, y
- Recibirá tarjetas de regalo por participar en este estudio y ayudarnos aprender como este programa trabajara para las familias. Usted podrá hacer esto al reunirse con el personal de *NET-Works* para contestar algunos cuestionarios acerca de la alimentación, actividades y hábitos de salud de su hijo(a). Esto será completado al comienzo del estudio y una vez al año por tres años,

Usted también podrá participar en:

- Clases de Crianza de *NET-Works* con otras familias en su comunidad, y
- Llamadas telefónicas y visitas a su casa por el personal de *NET-Works* que sirve como conector de familias.

Alguien del personal de *NET-Works* le llamara la próxima semana y le dirá mas acerca del estudio para ver si desea participar. Usted puede enviarnos un correo electrónico a NET-Works@umn.edu o puede llamar a la línea de estudio, al 612-624-9105 en cualquier momento para preguntar más acerca de este estudio. Por favor llámenos si no desea participar. La participación en este estudio es voluntaria. Su decisión no afectara el cuidado que recibe su familia en nuestra clínica.

Gracias por su tiempo y consideración.

Sinceramente,

Laurel Cederberg, MD
HealthPartners, Como

Simone French, PhD
Investigador Principal
University of Minnesota

Nancy Sherwood, PhD
Investigador Principal
HealthPartners Research Foundation

NET-WORKS

Our mission is to discover and accelerate the use of knowledge to improve the health and health care of our members, patients and community.

Appendix L

NET-Works Trial Invitation Letter (Cederberg) English

HealthPartners®
Research Foundation

8170 33rd Avenue South Mail Stop: 21111R
P.O. Box 1524
Minneapolis, MN 55440-1524
www.hprf.org

<Date>

Dear Parent or Legal Guardian of _____:

Our clinic and researchers at the University of Minnesota are working together on a research study called *NET-Works: Now Everybody Together for Amazing and Healthy Kids*. We are inviting your family to participate because your child is between the ages of 2 and 4 and has seen me for a visit in the past or has an upcoming well-child visit with me.

The *NET-Works* study helps Minnesota families of young children to develop positive parenting practices for healthy child growth and school readiness.

If you join, you will:

- Receive advice from your provider about ways to help your child be healthy, and
- Receive gift cards for taking part in this study and helping us learn how the program works for families. You would do this by meeting with *NET-Works* staff to answer some surveys about your child's eating, activity, and health habits. This will be done at the beginning of the study and then once a year for 3 years.

You may also get to participate in:

- *NET-Works* parenting classes with other families in your community, and
- Phone calls and home visits with a personal *NET-Works* Family Connector.

One of the *NET-Works* staff will call you in the next week to tell you more about the study and see if you would like to participate. You may send an e-mail to NET-Works@umn.edu or call the study line, at 612-624-9105 at any time to ask about the study. Please contact us if you choose *not* to participate. Taking part in this study is voluntary. Your decision will not affect the care your family receives at our clinic.

Thank you for your time and consideration.

Sincerely,

Laurel Cederberg, MD
HealthPartners, Como

Simone French, PhD
Lead Researcher
University of Minnesota

Nancy Sherwood, PhD
Lead Researcher
HealthPartners Research Foundation

NET-WORKS

Our mission is to discover and accelerate the use of knowledge to improve the health and health care of our members, patients and community.

Appendix M

NET-Works Main Study Consent Spanish

"NET-Works": Ahora Todos Juntos Para Niños Mas Sanos e Increíbles
Formulario de Consentimiento del Estudio Principal

Información
Usted esta invitado a participar en un estudio de investigación que se trata de ayudar a familias con niños jóvenes para que hagan decisiones mas sanas que durarán toda la vida. El propósito del estudio es para averiguar si los padres quien recibe mensajes y apoyo por su médico, clases de crianza comunitarias, y un conector de familias entrenado puedan realizar cambios en el hogar para ayudar a su hijo desarrollar hábitos saludables y prepararse para la escuela. El estudio durará 3 años. Usted y su hijo(a) pueden decidir la terminación de su participación en cualquier momento.

Estamos invitando a su familia a participar porque su hijo(a) esta entre las edades de 2 a 4 años y ustedes atienden una clínica Family Medicine Clinic afiliada con la Universidad de Minnesota, HealthPartners Clinic, Hennepin County Medical Center Clinic, o Children's Hospital of Minnesota Clinic.

El estudio está dirigido por Simone A. French, PhD, de la División de y Epidemiologia y Salud Comunitaria de la Universidad de Minnesota, y Nancy E. Sherwood, PhD, de la Fundación para la investigación de HealthPartners. El estudio se financia por los National Institutes of Health (NIH, Institutos Nacionales de la Salud) en Washington, DC y es parte de un estudio más grande de múltiples sitios.

Procedimientos para el Niño(a) y Adulto Participantes
Si usted decide a participar en el estudio, se le pedirá cumplir con lo siguiente:

1. Visita en su casa por personal de investigación entrenado para determinar su elegibilidad para el estudio.
El personal de investigación entrenado llegará a su casa para medir la altura y el peso de su hijo(a). Su familia puede o no puede ser elegible para participar en el estudio basado en esta información.

2. Completar un juego completo de mediciones.
Si su familia es elegible y usted acepta participar en el estudio, le pediremos a usted y su hijo para completar juegos de visitas para mediciones en casa al principio del estudio, después de 1 año, después de 2 años y después de 3 años de estar en el estudio. Estas mediciones incluyen:

a) La estatura y peso de usted y su hijo(a),
b) Circunferencia de la cintura de su hijo (hecho con una cinta métrica),
c) Una medida del pliegue cutáneo en la parte posterior del brazo de su hijo,
d) Una encuesta para aprender más sobre sus creencias acerca de la actividad física, la nutrición y sus prácticas de crianza (por ejemplo, reglas familiares y estilos de crianza),
e) 3 entrevistas sobre el alimentación de su hijo(a) durante el día anterior,

f) Usted y su hijo(a) tendrán puestos un Actigrafo (un dispositivo pequeño como podómetro que mide actividad) por 7 días para ayudarnos aprender mas sobre sus actividades. Se pedirá que usted y su hijo(a) tengan puestos los Actigrafos por 7 días adicionales si los dispositivos no se llevan puestos por suficientes días al principio,
g) El recogimiento de información sobre los alimentos y bebidas en su casa.
h) Dos pequeñas muestras de cabello de su hijo, cada uno de menos de ¼ del grosor de un lápiz, se cortará desde la parte posterior de la cabeza. Los cortes se realizan por debajo de varias capas de pelo para que no se pueda ver que se le había cortado el pelo. Esto se hace para verificar si el cortisol, que se utiliza para medir el desarrollo del niño, el estrés, y otros resultados importantes para la salud a través del tiempo. No vamos a compartir los resultados de esta muestra con usted o con su médico. La muestra de cabello se almacena en un lugar seguro, con cierre en la Universidad de Minnesota. Cuando la muestra de cabello está listo para ser procesado, será sin identificación, significando que no se le aplicara ninguna información personal como nombre o fecha de nacimiento. La muestra de cabello será completamente destruida en el procesamiento y ninguna otra información puede ser tomada de los cabellos,
i) Tareas breves de desarrollo de su hijo y la preparación para la escuela (por ejemplo, conocimiento de las palabras, las habilidades visuales), usted recibirá una carta de seguimiento o una llamada telefónica que le indica cómo su hijo grado en estas tareas y la información de referencia si sea necesario.

Una vez más, cada una de estas medidas se recogerán al inicio del estudio, después 1 año, después de 2 años, y después de 3 años de estar en el estudio para ayudarnos a aprender más sobre cómo las mentes y los cuerpos de los niños crecen a través del tiempo y para aprender acerca de los efectos del programa de NET-Works.

Como parte de nuestro estudio vamos a estar buscando en el expediente clínico de su hijo durante el tiempo que esté en el estudio y durante 2 años después de que concluya el estudio para averiguar acerca de los beneficios potenciales para la salud de los participantes en el estudio. Cualquier revisión de sus expedientes se llevará a cabo por miembros del personal de estudio, que son empleados de su grupo médico (Universidad de Minnesota, afiliado Family Medicine, HealthPartners, Hennepin County Medical Center, o Children's Hospital of Minnesota).

3. Asignación aleatoria a los grupos del estudio.
Después del primer juego de visitas para mediciones en casa, usted será colocado en uno de dos grupos del estudio. Usted tendrá una oportunidad igual de ser colocado en el "Grupo NET-Works" o en el "Grupo de Comparación." Usted recibirá una carta por correo y una llamada telefónica del seguimiento informándole su asignación en grupo.

- ***Grupo NET-Works***: Las familias en este grupo participarán en clases de crianza comunitarias, visitas domiciliarias, y llamadas telefónicas cada año del programa

de 3 años para hablar acerca de alimentación saludable, actividad y crianza de los hijos.

Cada una de las visitas domiciliarias se grabara por cinta audio para propósitos de evaluación.

- **Grupo de comparación**: Las familias en este grupo seguirán su horario habitual de visitas médicas. Ellos no recibirán las llamadas telefónicas adicionales, visitas domiciliarias, o clases de crianza comunitarias.

Procedimientos para Otros Miembros de la Familia:

A todos los otros miembros de familia que viven en la casa y quiénes están en la casa durante la primera visita para mediciones en casa, se les pedirá tomar mediciones de su altura y peso. Ellos que estén de acuerdo con esto en la primera visita para mediciones en casa también se les pedirán que hagan las mismas medidas en las visitas para mediciones en casa en el año 1, año 2, y año 3.

Riesgos y Beneficios

Su familia puede beneficiar o no beneficiara de este estudio. No sabemos si las actividades serán útiles. Por eso realizamos el estudio.

Los beneficios posibles del estudio incluyen aprendiendo maneras de ayudar a su hijo(a) a desarrollar hábitos saludables, incluyendo una dieta sana y ser activo físicamente.

La información que aprendamos de este estudio podrá beneficiar a otros niños en el futuro.

Con cada estudio de investigación se puede presentar un elemento de riesgo. El elemento de riesgo de este estudio es mínimo. El programa NET-Works podrá ayudar a padres hacer cambios pequeños en casa para ayudar a sus hijos desarrollar hábitos saludables de la vida incluyendo actividad física. Hay un riesgo pequeño de herida asociada con el aumento de la actividad física. También hay riesgos pequeños que otros cambios podrán afectar negativamente la crianza de su hijo(a) (como subida o bajada de peso). Trabajaremos con usted y el doctor de su hijo(a) para comprobar y resolver cualquier preocupaciones que tenga. Usted se puede sentir incomodo(a) responder a preguntas personales sobre su familia o hablar sobre asuntos con su doctor o conector de familias. Usted puede omitir cualquier pregunta que no quiere responder o puede terminar su participación en el estudio en cualquier momento. Mientras que tantos niños les gustaría participar en las tareas de desarrollo, si su hijo se convierte en aburrido o frustrado, descansos serán tomados, y pequeñas premios serán ofrecidos (por ejemplo, pegatinas) para ayudarlo/la participar. Su hijo(a) puede omitir las tareas o dejar de participar en cualquier parte de la evaluación.

Compensación

Para compensarle por su tiempo como participante en el estudio, todos los participantes que completen las visitas para mediciones en casa recibirán hasta un total de $200 en tarjetas de regalo:

- Hasta $50 por el primero juego de visitas para mediciones en casa
- Hasta $50 por juego de visitas para mediciones en casa el 1er año
- Hasta $50 por el juego de visitas para mediciones en casa en el 2 año
- Hasta $50 por el juego de para mediciones en casa en el 3 año

Por cada de las visitas para mediciones en casa, el pago se hará como sigue:

-Tarjeta de regalo de $10 se dará al terminar Visita Domiciliaria numero 1
-Tarjeta de regalo de $10 se dará al terminar Visita Domiciliaria numero 2
- Visita 3 se hará en su casa o por teléfono. Le daremos tarjeta de regalo de $30 si todas las medidas están completamente terminadas y verificadas por el personal del estudio. La tarjeta de regalo se enviará por correo dentro de la semana después de la recolección de datos se ha completado y verificado

El pago no depende de si los padres y los niños asignados en Grupo NET-Works de Clases y Conector de Familias participen en las actividades del grupo.

Al Reporte Obligatorio
Todo el personal de NET-Works son "denunciantes bajo mandato." Esto significa que la ley estatal de Minnesota exige el reportaje de abuso presunto sexual/físico y/o abandono por individuos. Los informes de abuso presunto sexual/físico y/o abandono serán hechos a la agencia de bienestar local, departamento de policía o sheriff del condado.

Confidencialidad
Toda la información recogida como parte de este estudio es confidencial. La información será identificada solamente por código. Cualquier informe o publicaciones presentarán la información agrupada solamente, no la información sobre individuos. Los datos pueden ser compartidos con otros investigadores y científicos no directamente parte de este estudio. Otros científicos pueden solicitar datos de este estudio. Datos serán proporcionados sólo después de asegurar que su nombre y otra información de identificación no serán compartidos con los investigadores. Esto significa que pueden mirar algúns de la dat pueden mirar 444444444

Certificado de Confidencialidad
Los investigadores han obtenido una protección jurídica especial de NIH (Institutos Nacionales de la Salud), los financiadores de esta investigación, llamado un "Certificado de Confidencialidad." Los datos que se recopilan de familias en el estudio están protegidos de ser compartida con las autoridades legales por este certificado. Las autoridades judiciales no pueden ver ninguna información personal acerca de cualquier persona inscrita en el estudio. Esto significa que su información personal no puede ser mirada por ninguna autoridad legítima o autoridad de aplicación de la ley.

Información adicional acerca del estudio
Una descripción de este ensayo clínico estará disponible en http://www.ClinicalTrials.gov, como requerido por la ley de EEUU. Este sitio de Web no incluirá información que pueda identificarle. A lo sumo, el sitio Web incluirá un resumen de los resultados. Puede buscar en este sitio Web en cualquier momento.

Contactos y Cuestiones
Si usted tiene cualquier pregunta acerca del estudio, puede pedirles ahora. Si usted tiene cualquier pregunta sobre el estudio más tarde, por favor póngase en contacto con Simone A. French, PhD, a la Universidad de Minnesota, División de Epidemiologia y Salud Comunitaria (612-626-8594). Si usted tiene cualquier pregunta o preocupaciones con respecto al estudio y le gustaría hablar con alguien distinto de los investigadores, por favor póngase en contacto con la Línea de Abogado de los Sujetos de Investigación, D528 Mayo, 420 Delaware Street Southeast, Minneapolis, MN 55455 (612-625-1650).

Declaración de Consentimiento para el Niño(a) y Adulto Participante

Estoy de acuerdo en tomar parte en el estudio de investigación descrito anteriormente. He preguntado cualquier pregunta que tenia y he sido dado respuestas. Un traductor de estudio capacitado fue proporcionado según sea necesario. Doy mi consentimiento para participar en el estudio. Al firmar este formulario, no renuncia a ninguno de mis derechos legales o la puesta en libertad cualquier persona involucrada en la investigación de su responsabilidad por negligencia. Me han dado una copia de este formulario de consentimiento para mis registros. Doy mi consentimiento para que mi niño participe en este estudio.

Adulto No. 1/Nino(a) que consiente participar en el estudio completo de 3 años

Nombre de Participante (adulto) Fecha de Nacimiento (m/d/a)

Firma de Participante (adulto) Fecha de la Firma

Relación al niño(a) que participa en el estudio completo

Nombre del niño(a) que participa en el estudio completo Fecha de Nacimiento (m/d/a)

Nombre de persona que obtiene consentimiento (miembro del equipo de investigación)

Firma de persona que obtiene consentimiento (miembro del equipo de investigación) Fecha de la Firma

Adulto No. 2 que consiente participar en el estudio completo de 3 años

Nombre de Participante (adulto) Fecha de Nacimiento (m/d/a)

Firma de Participante (adulto) Fecha de la Firma

Relación al niño(a) que participa en el estudio completo

Traducción proporcionada por:

Nombre Firma

Copies to: Participants Researchers' file

Declaración de Consentimiento para Otros Miembros de la Familia
Consentimiento de otros adultos y hermanos o hermanas para mediciones de estatura y peso durante este estudio de 3 años.

He leído el formulario anterior y doy mi consentimiento para que mi altura y peso sean medidas en la primera serie de visitas "Measure-Me" y en las visitas de "Measure-Me" en el año 1, año 2 y año 3. Un traductor capacitado fue ofrecido como sea necesario.

Adultos (edades 18 anos y mas)

Nombre (Adulto)	Firma	Fecha
Relación al niño(a) que participa en el estudio completo		Fecha de Nacimiento

Nombre (Adulto)	Firma	Fecha
Relación al niño(a) que participa en el estudio completo		Fecha de Nacimiento

Nombre (Adulto)	Firma	Fecha
Relación al niño(a) que participa en el estudio completo		Fecha de Nacimiento

Nombre (Adulto)	Firma	Fecha
Relación al niño(a) que participa en el estudio completo		Fecha de Nacimiento

Niños (de 7 a 17 años de edad)

Nombre (niño(a)/ hermano(a))	Nombre de adulto dando consentimiento	Fecha de Nacimiento del niño(a)
Firma (niño(a)/ hermano(a))	Firma de adulto dando consentimiento	Fecha
Relación al niño(a) que participa en el estudio completo		

Nombre (niño(a)/ hermano(a))	Nombre de adulto dando consentimiento	Fecha de Nacimiento del niño(a)
Firma (niño(a)/ hermano(a))	Firma de adulto dando consentimiento	Fecha
Relación al niño(a) que participa en el estudio completo		

Nombre (niño(a)/ hermano(a))	Nombre de adulto dando consentimiento	Fecha de Nacimiento del niño(a)
Firma (niño(a)/ hermano(a))	Firma de adulto dando consentimiento	Fecha
Relación al niño(a) que participa en el estudio completo		

Nombre (niño(a)/ hermano(a))	Nombre de adulto dando consentimiento	Fecha de Nacimiento del niño(a)
Firma (niño(a)/ hermano(a))	Firma de adulto dando consentimiento	Fecha
Relación al niño(a) que participa en el estudio completo		

Niños (de 2 a 6 años de edad)

Nombre (niño(a)/ hermano(a)) Nombre de adulto dando consentimiento Fecha de Nacimiento del niño(a)

Firma de adulto dando consentimiento Fecha

Relación al niño(a) que participa en el estudio completo

Nombre (niño(a)/ hermano(a)) Nombre de adulto dando consentimiento Fecha de Nacimiento del niño(a)

Firma de adulto dando consentimiento Fecha

Relación al niño(a) que participa en el estudio completo

Nombre (niño(a)/ hermano(a)) Nombre de adulto dando consentimiento Fecha de Nacimiento del niño(a)

Firma de adulto dando consentimiento Fecha

Relación al niño(a) que participa en el estudio completo

Nombre (niño(a)/ hermano(a)) Nombre de adulto dando consentimiento Fecha de Nacimiento del niño(a)

Firma de adulto dando consentimiento Fecha

Relación al niño(a) que participa en el estudio completo

Traducción proporcionada por:

Nombre Firma

Copies to: Participants Researchers' file

Appendix M

NET-Works Main Study Consent English

"NET-Works": Now Everybody Together for Amazing and Healthy Kids
Main Study Consent Form

Background
You are invited to take part in a research study about helping families with young children make healthy choices that will last a lifetime. The purpose of the study is to find out if parents who receive messages and support from their primary doctor, community parenting classes, and a trained family home visitor can make changes at home to help their child develop healthy habits and get ready for school. The study will last for 3 years. You and your child can decide to end your participation at any time.

You are being asked to take part in this study because your child is between the ages of 2 and 4 years and you attend a University of Minnesota-affiliated Family Medicine Clinic, HealthPartners Clinic, Hennepin County Medical Center Clinic, or Children's Hospital of Minnesota Clinic.

The study is being led by Simone A. French, PhD from the University of Minnesota's Division of Epidemiology & Community Health and Nancy E. Sherwood, PhD from the HealthPartners Research Foundation. The study is funded by the National Institutes of Health (NIH) in Washington, DC and is part of a larger, multi-site study.

Procedures for Participating Child and Adult
If you choose to take part in the study, you will be asked to do the following:

1. Visit by trained research staff in your home to determine study eligibility.
Trained research staff will come to your home to measure your child's height and weight. Your family may or may not be eligible to take part in the study based on this information.

2. Complete a set of measurements.
If your family is eligible and you agree to be in the study, we will ask you and your child to complete a set of home measurement visits at the beginning of the study, after 1 year, after 2 years, and after 3 years of being in the study. These measurements include:

a) You and your child's height and weight,
b) Your child's waist circumference (using a tape measure),
c) A skinfold measure on the back of your child's upper arm,
d) A survey to learn more about your beliefs about physical activity, nutrition, and your parenting practices (e.g. family rules and parenting styles),
e) 3 interviews about your child's eating during the previous day,
f) You and your child wearing an Actigraph (a small device on a belt that measures activity) for 7 days to help us learn more about your activity patterns. You and your child will be asked to wear the Actigraphs for 7 additional days if the devices were not worn for enough days the first time,
g) Collecting information about food and beverages in your home,

h) Two small samples of your child's hair, each less than ¼ the width of a pencil will be cut from the back of the head. The cuts are made underneath several layers of hair so that you cannot tell that any hair has been cut. This will be done to check cortisol, which is used to measure child development, stress, and other important health outcomes over time. We will not share the results of this sample with you or your doctor. The hair sample will be stored in a secure, locked location at the University of Minnesota. When the hair sample is ready to be processed, it will be de-identified, meaning it will not be labeled with any personal information like name or date of birth. The hair sample will be completely destroyed in processing and no other information can be taken from the hair,

i) Brief tasks of your child's development and school readiness (e.g., word knowledge, visual skills); you will get a follow-up letter or phone call telling you how your child did on these tasks and referral information if any is needed.

Again, each of these measures will be collected at the beginning of the study, after 1 year, after 2 years, and after 3 years of being in the study to help us learn more about how children's minds and bodies grow over time and learn about the effects of the NET-Works program.

As part of our study we will be looking at your child's medical record during the time you are in the study and for 2 years after the study is complete to find out about the potential health benefits of participating in the study. Any review of your records would be conducted by study staff members, who are employees of your medical group (University of Minnesota-affiliated Family Medicine, HealthPartners, Hennepin County Medical Center, or Children's Hospital of Minnesota).

3. Random assignment to study groups.
After your first set of home measurement visits, you will be put into one of two study groups. You will have an equal chance of being placed in either the "*NET-Works*" group or the "Comparison" group. You will receive a letter in the mail and a follow-up phone call informing you of your group assignment.

- ***NET-Works group***: Families in this group will take part in monthly community parenting classes, home visits, and phone calls each year of the 3-year program to talk about healthy eating, activity, and parenting.

  Each of the sessions will be audiotaped for evaluation purposes.

- ***Comparison group***: Families in this group will follow their usual schedule of medical visits. They will not receive the additional phone calls, home visits, or community parenting classes.

Procedures for Other Family Members
All other family members who live in the household and who are at the home during the first home measurement visit will be asked to have their height and weight measured. Those who agree to this at the first home measurement visit will also be asked to do the same measurements at the year-1, year-2, and year-3 home measurement visits.

Risks and Benefits

Your family may or may not benefit from this study. We do not know if the study activities will be helpful. That is why we are doing the study.

The possible benefits of the study include learning ways to help your child develop healthy habits including eating a healthy diet and being physically active.

The information we learn from this study may benefit other children in the future.

With any research study there may be an element of risk. The risk in this study is minimal. The NET-Works program may help parents make small changes at home to help children develop healthy lifestyle habits including physical activity. There is a small risk of injury associated with increases in physical activity. There is also a small risk that these changes could have a negative effect on children's growth (e.g. weight gain or loss). We will work with you and your child's doctor to check for and address any concerns. You may feel uncomfortable answering personal questions about your family or talking about issues with your doctor or family connector. You may skip any questions you do not want to answer or leave the study at any point. While many children enjoy participating in developmental tasks, if your child becomes bored or frustrated, breaks will be taken and small rewards offered (e.g. stickers) to help him/her engage. Your child may skip tasks or stop participating in any part of the assessment.

Compensation

To compensate you for your time as a participant in the study, all participants who complete the home measurement visits will receive up to a total of $200 in gift cards:

- Up to $50 for the first set of home measurement visits
- Up to $50 for the year-1 home measurement visits
- Up to $50 for the year-2 home measurement visits
- Up to $50 for the year-3 home measurement visits

For each set of measurement visits, payment will be made as follows:

- $10 gift card given at the home upon completion of Home Visit #1
- $10 gift card given at the home upon completion of Home Visit #2
- Visit #3 will be done either at your home or by phone. You will be given a $30 gift card if all measures are fully completed and verified by study staff. The gift card will be mailed within the week after data collection is completed and verified.

Payment is not dependent on whether parents and children assigned to the NET-Works Classes & Family Connector group attend and participate in the group activities.

Mandated Reporting

All of the NET-Works staff are "mandated reporters." This means that Minnesota State law mandates the reporting of alleged physical/sexual abuse and/or neglect by individuals. Reports of alleged physical/sexual abuse and/or neglect will be made to the local welfare agency, police department or county sheriff.

Confidentiality
All information gathered as part of this study is confidential. Information will be identified by a code number only. Any reports or publications will present only grouped information, not information on individuals. Data may be shared with other researchers and scientists not directly involved in the study. Other scientists may request data from this study. Data will be released only after ensuring that you or your child's name and other identifying information are not given to any researchers. This means they can look at some of the information we collect, but they will not be able to see any information about who you are (e.g. birthdates, addresses, names). For families participating in the NET-Works group, information on progress of program activities will be shared with your doctor.

Voluntary Nature of the Study
Your participation in this study is voluntary. You may withdraw from the study at any time without affecting your relationship with the University of Minnesota-affiliated Family Medicine Clinics, HealthPartners Clinics, Hennepin County Medical Center Clinics, Children's Hospital of Minnesota Clinics, the researchers, or your doctor. If you decide to stop, please talk with the Project Director at 612-624-9378 or 612-624-9105.

Certificate of Confidentiality
The researchers have obtained a special legal protection from NIH, the funders of this research, called a "Certificate of Confidentiality". The data that is gathered from families in the study are protected from being shared with legal authorities by this Certificate. Legal authorities cannot see any personal information about anyone enrolled in the study. This means that your personal information cannot be looked at by any legal or law enforcement authority.

Additional Information about the study
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Contacts and Questions
If you have any questions about the study, you may ask them now. If you have any questions about the study later, please contact Simone A. French, PhD, at the University of Minnesota, Division of Epidemiology & Community Health (612-626-8594). If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact the Research Subjects' Advocate Line, D528 Mayo, 420 Delaware Street Southeast, Minneapolis, MN 55455 (612-625-1650).

Statement of Consent for Participating Child and Adult

I agree to take part in the research study described above. I have asked any questions I had and have been given answers. A trained study translator was provided as needed. I consent to take part in the study. By signing this form, I do not give up any of my legal rights or release anyone involved in this research study from their responsibility for negligence. I have been given a copy of this consent form for my records. I consent to have my child participate in this study.

Adult #1/Child consenting to participate in the full 3-year study

Name of Participant (adult) Birthdate (m/d/y)

Signature of Participant (adult) Date of Signature

Relationship to child participating in the full study

Name of child participating in the full study Birthdate (m/d/y)

Name of person obtaining consent (study team member)

Signature of person obtaining consent (study team member) Date of signature

Adult #2 consenting to participate in the full 3-year study

Name of Participant (adult) Birthdate (m/d/y)

Signature of Participant (adult) Date of Signature

Relationship to child participating in the full study

Translation provided by:

Name Signature

Copies to: Participants Researchers' file

Statement of Consent for Other Family Members

Consent of other adults and brothers or sisters for height and weight measurements during the 3-year study.

I have read the above form and consent to have my height and weight measured during the first set of "Measure-Me" visits and the year-1, year-2, and year-3 "Measure-Me" visits. A trained study translator was provided as needed.

Adults (age 18 and older)

Name (adult)	Signature	Date
Relationship to child participating in the full study		Birthdate

Name (adult)	Signature	Date
Relationship to child participating in the full study		Birthdate

Name (adult)	Signature	Date
Relationship to child participating in the full study		Birthdate

Name (adult)	Signature	Date
Relationship to child participating in the full study		Birthdate

Children (age 7 to 17)

Name (child/sibling)	Name of consenting adult	Child Birthdate
Signature (child/sibling)	Signature of consenting adult	Date
Relationship to child participating in the full study		

Name (child/sibling)	Name of consenting adult	Child Birthdate
Signature (child/sibling)	Signature of consenting adult	Date
Relationship to child participating in the full study		

Name (child/sibling)	Name of consenting adult	Child Birthdate
Signature (child/sibling)	Signature of consenting adult	Date
Relationship to child participating in the full study		

Name (child/sibling)	Name of consenting adult	Child Birthdate
Signature (child/sibling)	Signature of consenting adult	Date
Relationship to child participating in the full study		

Children (age 2 to 6)

Name (child/sibling)	Name of consenting adult	Child Birthdate
	Signature of consenting adult	Date

Relationship to child participating in the full study

Name (child/sibling)	Name of consenting adult	Child Birthdate
	Signature of consenting adult	Date

Relationship to child participating in the full study

Name (child/sibling)	Name of consenting adult	Child Birthdate
	Signature of consenting adult	Date

Relationship to child participating in the full study

Name (child/sibling)	Name of consenting adult	Child Birthdate
	Signature of consenting adult	Date

Relationship to child participating in the full study

Translation provided by:

Name	Signature

Copies to: Participants Researchers' file

Appendix N

Interview Questions

Project: Disclosure vs. Understanding
Laura Pigozzi

1. Can you explain what you are being asked to do in this study?

1.1 What do you think of this?

2. What is the goal of this study?

3. Are there any risks involved with being in this study?

3.1 (if affirmative) What are they?

4. Will there be any benefits for you by being in the study?

4.1 (if affirmative) What are they?

5. How long does this study last?

6. How long are you required to stay in the study?

7. Are there any questions you would want to ask José?

8. Is there information you want to know about this study that José did not tell you?

9. Would you choose to participate in this study?

(if no) What reasons might you have for not participating?

10. What did you like about how the information was presented?

11. What did you not like?

12. Can you think of other ways Jose could have explained things to help with understanding?

13. If you were responsible for explaining a study such as this, how would you do it? What would that look like?

14. How might you invite Latinos to be in such a study?

Appendix O

Demographpic Information and SAHLSA-50 Scores

Phase 1

Age	Country of origin	Education	Level English	SAHLSA score	Years in United States
36–45 years	Mexico	more than 12 years	5	50	11–15 years
46–55 years	Mexico	1–6 years	2	41–45	11–15 years
46–55 years	Ecuador	10–12 years	4	50	11–15 years
more than 65 years	Mexico	no formal education	1	21–30	less than 1 year
more than 65 years	Mexico	no formal education	1	21–30	less than 1 year
36–45 years	Mexico	1–6 years	3	41–45	11–15 years
26–35 years	Mexico	1–6 years	1	41–45	16–20 years
26–35 years	Mexico	more than 12 years	3	38–40	11–15 years
36–45 years	Mexico	1–6 years	1	38–40	11–15 years
36–45 years	Mexico	7–9 years	1	41–45	16–20 years
18–25 years	Mexico	10–12 years	3	38–40	5–10 years
18–25 years	Mexico	10–12 years	3	41–45	3–5 years
36–45 years	Mexico	more than 12 years	2	41–45	5–10 years
more than 65 years	Mexico	1–6 years	1	38–40	11–15 years
46–55 years	Mexico	more than 12 years	5	46–49	more than 25 years

Demographpic Information and SAHLSA-50 Scores

Phase 2

Age	Country of origin	Education	Level of English	SAHLSA score	Years in United States
36–45	Mexico	1–6 years	1	39	11
46–55	Ecuador	1–6 years	3	38	30
36–45	Mexico	more than 12 years	3	42	14
16–55	Mexico	10–12 years	3	43	17
56–65	Ecuador	1–6 years	1	39	18
36–45	Mexico	more than 12 years	3	47	11
56–65	Mexico	1–6 years	1	46	5–10
26–35	Mexico	more than 12 years	3	41	12
36–45	Mexico	7–9 years	4	37	15
36–45	Ecuador	10–12 years	3	43	13
18–25	USA	more than 12 years	5	48	
56–65	Mexico	1–6 years	1	38	5–10
46–55	Mexico	7–9 years	1	43	3–5
55–65	Mexico	more than 12 years	2	48	3–5
36–45	Mexico	1–6 years	1	39	5–10
56–65	Mexico	7–9 years	2	25	41
36–45	Mexico	7–9 years	2	20	22
46–55	Mexico	10–12 years	1	42	15
36–45	Mexico	more than 12 years	2	45	16
18–25	Mexico	10–12 years	4	43	1–3
18–25	Mexico	10–12 years	1	41	3–5

Phase 2

Age	Country of origin	Education	Level of English	SAHLSA score	Years in United States
56–65	Mexico	7–9 years	2		40
36–45	Mexico	10–12 years	1		5–10
> 65	Mexico	0	1		3–5
36–45	Mexico	10–12 years	4		5–10
>65	Mexico	1–6 years	1		<1
36–45	Mexico	more than 12 years	3		5–10
36–45	Mexico	more than 12 years	3		14
36–45	Mexico	1–6 years	2		10
		Note: The SALSA forms got separated from the demographics sheets.			
				29	
				45	
				47	
				48	
				41	
				42	
				49	
				41	
>65	Mexico	more than 12 years	4	48	36
46–55	Ecuador	more than 12 years	3	48	5–10
36–45	USA	more than 12 years	5	48	

Appendix P

Script for Priming Video

We are working with the doctors at the _____ clinic on the study. Our goal is to help kids develop healthy habits around food and activity and get ready for school. The study includes information from your child's doctor, and also the possibility of parenting classes close to home, and sessions with a family home visitor.

> Estamos trabajando con los doctores de la clínica _____. Nuestra meta es ayudarle a los niños a desarrollar hábitos saludables sobre los alimentos, la actividad física y sobre la preparación prescolar. Este estudio incluye información del doctor de su hijo, y también incluye la posibilidad de clases de la crianza cerca de su casa y también sesiones con un conector de familias.

The NET-Works study is designed to help parents with young children develop positive parenting practices for healthy child growth and school readiness. We hope that the study will not only be helpful to the parents who participate, but that what we learn will help other Minnesota families in the future.

> El estudio NET-Works se diseña para ayudarle a los padres con niños pequeños a desarrollar las prácticas positivas de crianza para el crecimiento sano del niño y la preparación escolar. Esperamos que el estudio no solo será útil para los padres que participan, pero lo que aprendemos ayudara otras familias de Minnesota en el futuro.

Ok, now, because this is a study, we will divide everyone into 2 groups. This is done by chance, like flipping a coin. We do this so that at the end of the 3 year study we can compare the groups and see how the program worked.

> Muy bien, ahora porque este es un estudio vamos a dividir a todas familias en dos grupos. Esto se determina al azar, como lanzamiento de la moneda. Hacemos esto para que al final de los 3 años podamos comparar los grupos y mirar como ha trabajado el programa.

So the 2 groups are: the NET-Works Group, and the Comparison Group.

> Los 2 grupos son: El grupo Net-Works y el Grupo de Comparación.

If you are in the Comparison Group your child's doctor would talk to you about healthy eating and activity at your annual well-child visit and you would complete the annual measurement visits, once a year, for 3 years.

> Si asignan a su familia al grupo de comparación el doctor de su hijo hablara con usted en la visita anual sobre comer mejor y mas saludable y también de la actividad física, y su familia completara las visitas anuales de "Measure-Me," una vez al año por 3 anos.

If you are assigned to the NET-Works Group, you would get this same information from your child's doctor and you would go to community parenting classes and you would receive home visits with a family connector. These classes and visits will be about helping your child get ready for school by eating healthy and being active. You would also complete the annual "Measure-Me" visits, once a year, for 3 years. Everyone who joins the study does the "Measure-Me" visits.

> Si se le asigna al Grupo NET-Works, usted recibirá la misma información del doctor de su hijo y usted ira a clases de crianza comunitarias y también recibirá visitas a su casa con un conector de familias. Estas clases y visitas serán para ayudar a su hijo a estar preparado para la escuela por modo de comer mas sano y ser mas activo. Su familia también completara las visitas "Measure-Me", una vez al ano por 3 años.

We are asking for a 3 year commitment from families. 3 years might sound like a long time, but we want to make the 3-year involvement as valuable as we can for your family. So, it is important that we know that families who decide to participate will be with the study for those 3 years.

> Pedimos a las familias que se comprometan al estudio por 3 años. 3 años se parece mucho tiempo, pero queremos que estos 3 años sean tan valiosos para su familia. Por eso, es importante que sepamos que las familias que deciden participar estarán con el estudio durante los próximos 3 anos.

So the first thing we would do is schedule a "Measure-Me" visit at your home where we will measure your child's height and weight and find out if your family is eligible for the study. If you're not eligible based on this information, we'll give you a $10 gift card to thank you for your time.

> Así que lo primero que haremos es programar la primera cita de "Measure-Me", donde tomaremos las medidas de estatura y peso de su hijo para verificar si su

familia sea elegible para este estudio. Si su familia no sea elegible, le daremos una tarjeta de regalo de $10 como agradecimiento para su tiempo.

If your family is eligible and wants to participate, we'll sign you up for the study and take some other measurements. This first "Measure-Me" visit will last about two hours. A week later we'll do a second "Measure-Me" visit to pick up some equipment and do some other measurements, and again this visit will last about another two hours.

Si su familia sea elegible y quiere participar, registramos a su familia para este estudio y tomaremos otras mediciones. Esta primera visita de "Measure-Me" durara aproximadamente 2 horas. Una semana después haremos la segunda visita de "Measure-Me" para recoger parte del equipo y tomaremos otras mediciones.

Being in a research study can be really interesting and fun, but there is also a commitment involved.

En estar en un estudio puede ser muy divertido e interesante, pero también implica responsabilidades.

It is a lot to consider, and I want you to think about whether this will be ok, or if it will be too much for your family. We try really hard to keep all families in the study for the full 3 years.

Hay mucho que considerar y quiero que piense si esto seria demasiado para su familia o si seria bien para ustedes. Queremos mantener a todas las familias en el estudio por los 3 años.

Appendix Q

Script for Consent Video

NET-Works Consenting Script

Background

What we'd like to do next is walk through the Consent Form to tell you about each part of the study, get your permission to participate, and see if you have any questions.

First, the purpose of this study is to find out if the two NET-Works programs we offer help parents with 2-4 year old children make changes at home to help their kids develop healthy habits and get ready for school. We will be working with you for 3 years.

Procedures

After you complete the first two or three visits you will be randomly put into one of two groups. This means that it is like a flip of a coin to determine getting into one group or the other. You will need to fully complete the first set of Measure-Me visits to be able to continue to the next phase of the study.

Because this is a research study we have two groups so that we can compare and see how our program is working and see how our families react to the program.

If you are put into the NET-Works Group, again this happens by chance; you will get to attend monthly parenting classes, home visits and phone calls each year of the 3-year program to talk about healthy eating, physical activity, and parenting.

If you are in the Comparison Group you will follow your usual schedule of medical visits. You won't receive additional phone calls or home visits.

We will ask that both groups, all families, do the same set of "Measure-Me" visits, where we will come to your house after 1 year, after 2 years and after 3 years of being in the study. You will need to complete all measures each year in order to receive the full $50 in gift cards to compensate you for your time.

Risks and Benefits

This is a relatively "low-risk" study. You may feel uncomfortable having your height and weight measured or answering some of the survey questions. But, remember that you can skip any questions you don't want to answer. There is also a small risk that increasing activity can lead to injury.

Your family may or may not benefit from the study, but we hope that you do. We hope you learn ways to keep your family healthy and active. We also hope that what we learn from your family will help other families in the future.

Compensation

To compensate you for your time, you'll receive up to $200 in gift cards over the next three years. You'll receive up to $50 for each set of Measure-Me visits. Remember, that in order to receive the $30 portion of the gift cards, both you and your child need to wear the activity monitors for a full week.

Mandated Reporting

The NET-Works staff members are mandated reporters. This means it is required of us to report any abuse or neglect we may see in a home.

Confidentiality

We keep all of your information private and confidential. We label all of your information with a study ID number and take off your name or other identifying information like birth date before sharing this with other researchers.

If you are in the NET-Works Group, we could share information about your progress with your doctor.

Voluntary Nature of the Study

It's important that you know your participation in this study is voluntary and you can stop at any time without it affecting your care at your clinic.

Certificate of Confidentiality

The study has special protection with regards to your personal information. Legal authorities will NOT be able to see any personal information about you. In other words, your personal information cannot be looked at by any legal or law enforcement authority.

Additional Information about the Study

A description of the study can be found online at www.clinicaltrials.gov if you're interested in looking up any information. This website will NOT contain any information that can identify you in any way.

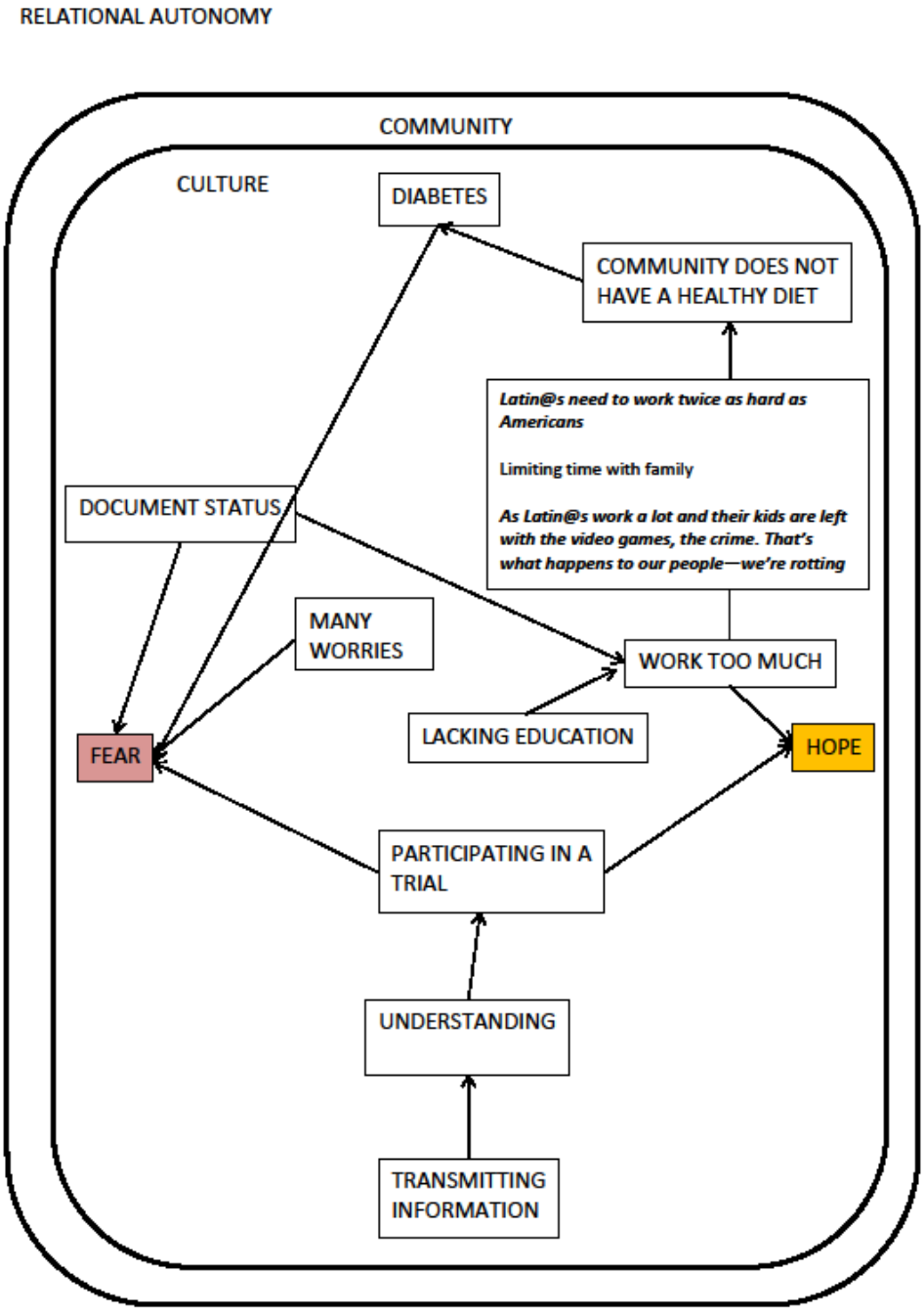
Contacts and Questions

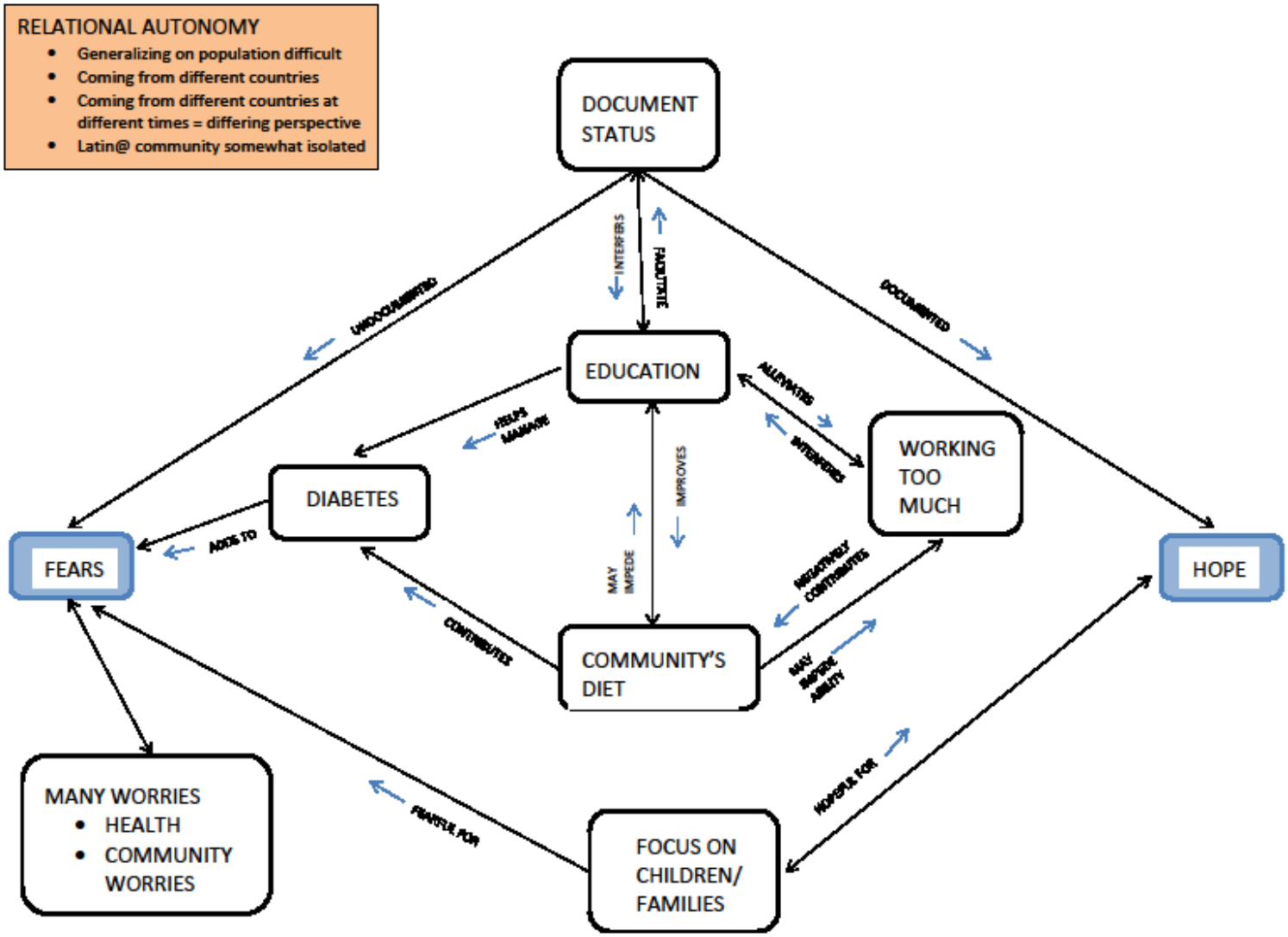
By signing this form it means that you understand what has been explained to you, and you agree for you and your child to take part in this study.

If you have any questions throughout the study, you can call our Project Director at this number (point to number in the first paragraph on pg. 3). If you would like to talk to someone outside of the study, we also have the number for our "Research Subjects Advocate Line" listed here (point to number in last paragraph on pg 3).

Appendix R

Evolution of the Conceptual Framework

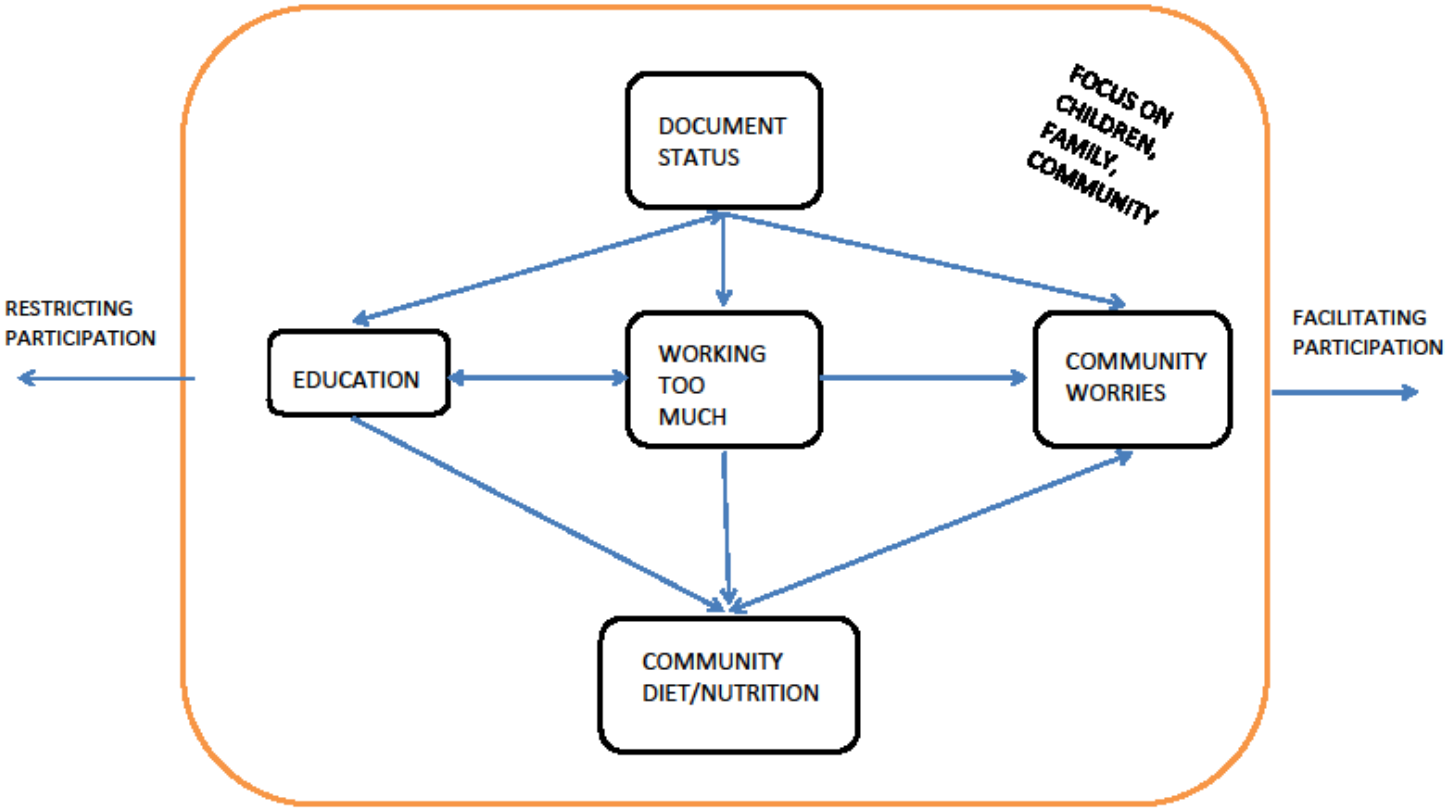


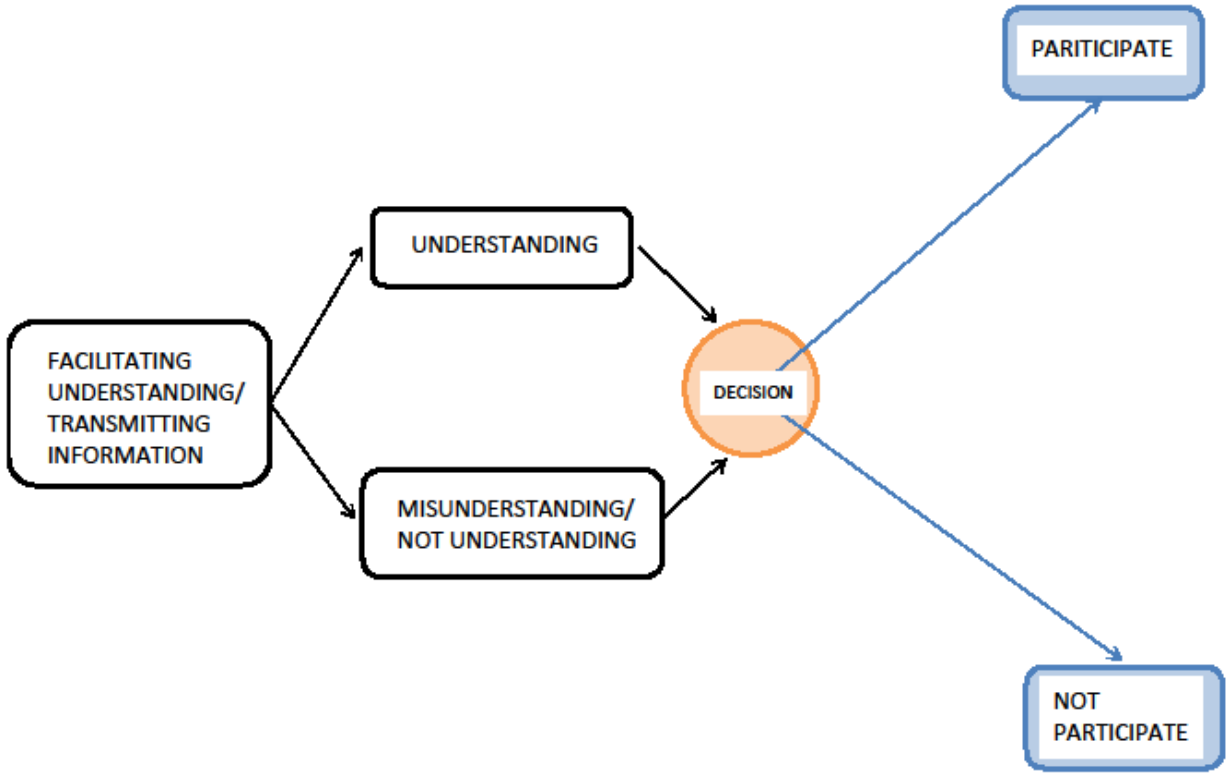

RELATIONAL AUTONOMY
Generalizing on population difficult
Coming from different countries
Coming from different countries at different times = differing perspective
Latin@ community somewhat isolated
DOCUMENT STATUS
INTERFERS
FACILITATE
UNDOCUMENTED
DOCUMENTED
EDUCATION
HELPS MANAGE
ALLEVIATES
INTERFERES
DIABETES
WORKING TOO MUCH
IMPROVES
MAY IMPEDE
ADDS TO
FEARS
HOPE
CONTRIBUTES
NEGATIVELY CONTRIBUTES
COMMUNITY'S DIET
MAY IMPROVE ABILITY
MANY WORRIES
HEALTH
COMMUNITY WORRIES
FEARFUL FOR
HOPEFUL FOR
FOCUS ON CHILDREN/ FAMILIES

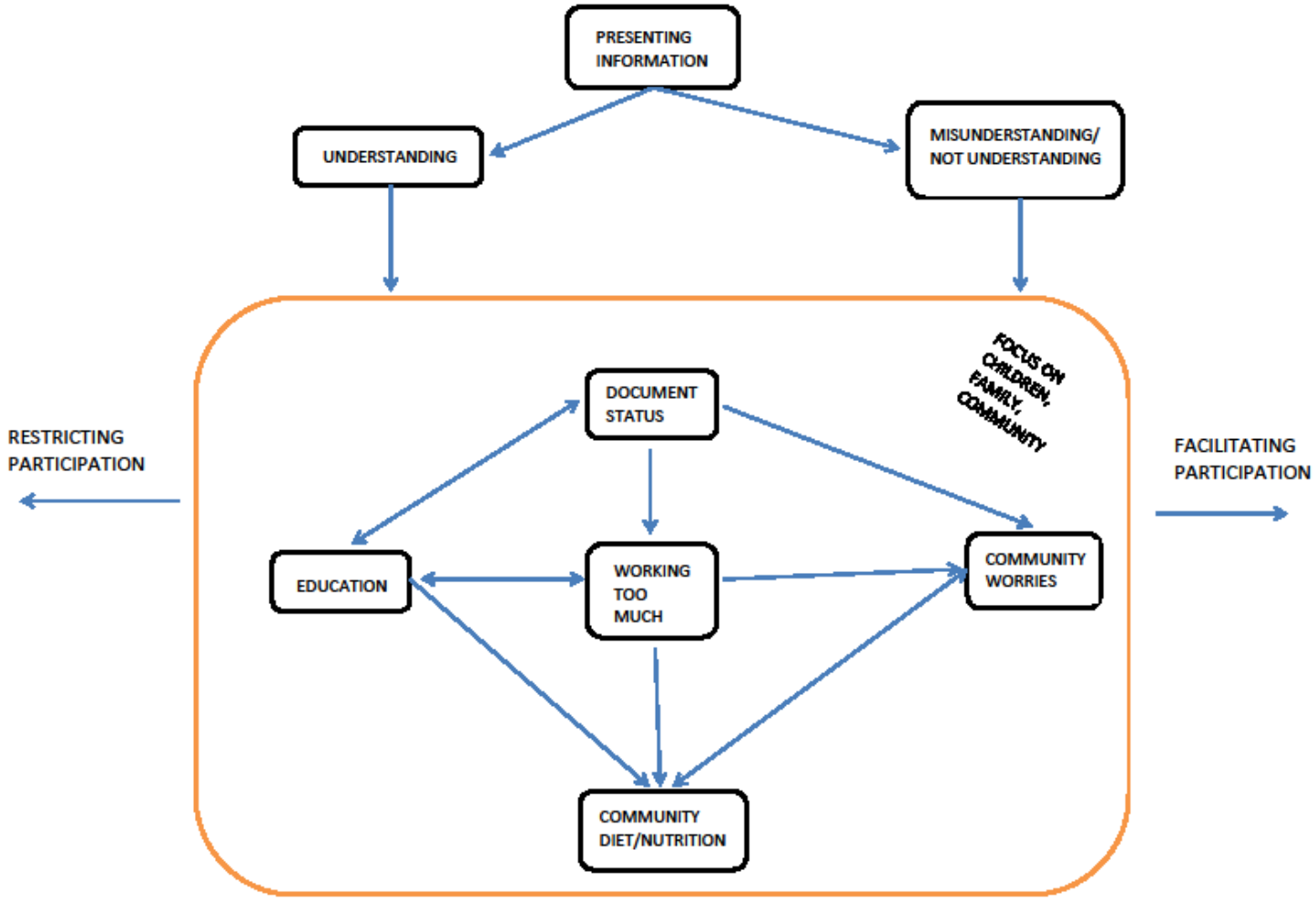
RELATIONAL AUTONOMY

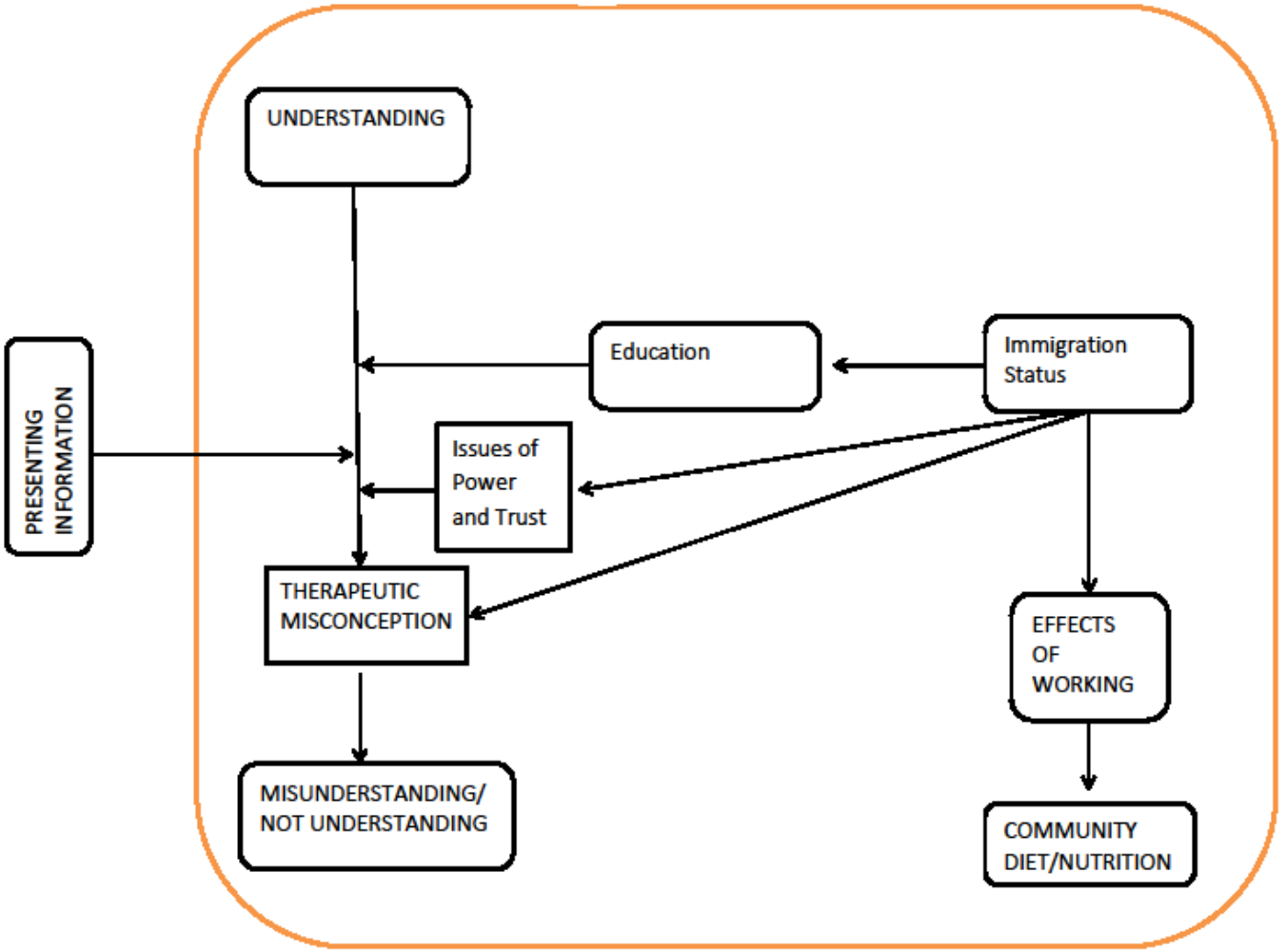
- Generalizing on population difficult
- Coming from different countries
- Coming from different countries at different times = differing perspective
- Latin@ community somewhat isolated

RHETORICAL CONTEXT




PARITICIPATE
UNDERSTANDING
FACILITATING UNDERSTANDING/ TRANSMITTING INFORMATION
DECISION
MISUNDERSTANDING/ NOT UNDERSTANDING
NOT PARTICIPATE


PRESENTING INFORMATION
UNDERSTANDING
MISUNDERSTANDING/ NOT UNDERSTANDING
FOCUS ON CHILDREN, FAMILY, COMMUNITY
DOCUMENT STATUS
RESTRICTING PARTICIPATION
FACILITATING PARTICIPATION
EDUCATION
WORKING TOO MUCH
COMMUNITY WORRIES
COMMUNITY DIET/NUTRITION


UNDERSTANDING
PRESENTING INFORMATION
Education
Immigration Status
Issues of Power and Trust
THERAPEUTIC MISCONCEPTION
EFFECTS OF WORKING
MISUNDERSTANDING/ NOT UNDERSTANDING
COMMUNITY DIET/NUTRITION

Appendix S

Recruitment Flyer Study 2 Spanish

Appendix S

Recruitment Flyer Study 2 English Translation

You are invited to participate

Consider taking part in this study. It is important to hear the opinions and suggestions of Latinos regarding medical research.

Who can participate? Parents with children 15 years or under.

The meetings will take place after the 11:30 am mass and the 6:00 pm mass. We will serve food. Children are welcome.

You will view two short videos and discuss them with the researcher.

You will be given a $15 Cub Foods Gift Certificate.

Questions?

Email Laura Pigozzi

pigoz002@umn.edu

This study is being conducted by Laura Pigozzi, University of Minnesota (IRB #1210P22682)

Appendix T

Recruitment Flyer Study 3 Spanish

Appendix T

Recruitment Flyer Study 3 English Translation

Usted Esta Invitado a Participar!

Diabetes is a common disease in the Latino community. The rate of diagnosed diabetes is 12.8% among all Latinos and 13.9% for Mexican Americans. Because of the high rate of this disease in this community it is important that Latinos are included in clinical trials to test diabetes medication.

The explanations of these trials are often hard to understand. We would like you to listen to an explanation of one diabetes trial and give us your opinions on how well it is explained.

The meetings will be after the 11:30 am mass and the 1:15 pm mass in the church on 11/9. We will serve food. Children are welcome.

We will give you $15 as appreciation for your time.

Would you like to participate?

Write an email to Laura Pigozzi

This study is being organized by Laura Pigozzi

University of Minnesota (IRB #1210P22682)

Appendix U

Original ACCORD Consent Transcript English

ACCORD Consent (55:07)

Well welcome thank you so much for coming to talk about the ACCORD study with us. I know we talked about the study over the telephone and I kind of summarized it and sent you out the consent form and I just want to go through it with you in detail with you today so you can get a good sense of whether this is something you'd like to participate in or not. Did you have a chance to look through the consent form that I sent you?

OK great! I'm just going to summarize – the whole purpose of this study is that we're trying to figure out the best way to treat people with Type 2 diabetes to reduce the risk of heart attack and stroke. Heart attack and stroke we know is two to four times greater among people with diabetes compared to those in the general population (1:05) So it's a pretty important question, if we can find a way to reduce that risk that will have very good implications for the future of treating diabetes. So we've invited you to join in this study and determine if you are eligible for this study. This study is sponsored by the National Heart, Lung and Blood Institute, it is part of the United States government and that just means that the money for this study comes from the government so taxes that we pay are going to support this study. The main doctor that's involved in this study and who started the study is Dr. Seaquist and she is a diabetes specialist here at the University. So we'll start off by going through the consent, please interrupt me at any point if you have questions or something does not seem clear because I'm happy to answer them along the way (2:06)

So we know that Type 2 diabetes is very common in North America and people with Type 2 diabetes have a higher chance of getting heart disease and stroke than people without diabetes. And so again, the purpose is to find the best ways to lower that risk in people with Type 2 diabetes. The ACCORD study is going to answer three questions. In diabetes we know that the level of blood sugar is too high so we want to know if lowering the blood sugar to a level that is normally targeted the way you would see your doctor right now compared to getting it lower than that, if that will reduce your risk of having heart attack and stroke. We know that people with diabetes often have high blood pressure as well and so the second question is to determine if lowering blood sugar to a lower level that's currently used in clinical practice, will that also reduce your risk of heart attack and stroke. And the third question is, we know that many people with

diabetes also have problems with their blood cholesterol or lipids, that's the fat that is in your blood and so we want to know if we treat a couple different components of your blood lipids compared to treating only one component, if that will reduce your risk of heart attack and stroke. And I'll go through that in a little more detail later in the consent process.

So the plan is if you were to enroll in the study you would be involved in the study until about June of 2009. However, (4:02) there's a safety monitoring board that reviews the results of the study and if they see any reason to stop the study earlier it could end earlier than that. We hope to recruit about 10,000 people across the U.S. and Canada from about 70 different clinics and the University of Minnesota site is hoping to have about 250. So what is actually going to happen if you participate in this study? We start off with a screening visit, that's when you take your medical history, talk about medical problems you've had in the past, look at your blood pressure, your blood sugars, and your cholesterol and we'll see if you would be eligible for this study. You'll have a short physical exam, a little bit of blood would be taken, about two teaspoons to check your kidney, liver and cholesterol (5:01) and some urine would be collected also (5:04) to look for protein. Now everybody would be involved in the diabetes part of the study but then we would also want you to be involved with either the cholesterol or the blood lipid portion or the blood pressure part of the study. So if you were involved in the blood pressure part then your own doctor would manage your cholesterol and if you were involved in the cholesterol part then your own doctor would manage your blood pressure. And we do stay in communication with your doctor throughout the entire study sending blood test results and keeping them up to date on what's going on.

The blood sugar treatment group, there are two options and it's a random assignment so let's say for instance we're flipping a coin there is half a chance that you would be in the intensive group and half a chance that you would be in the standard group. We don't have any say in which group you would be involved in and you don't have any say so we really want to be sure that you feel comfortable in either group because it is a 50 – 50 chance that you would go in either group. The intensive goal would be to lower your blood sugar lower than is currently recommended and the standard goal is to try to keep your blood sugar at a level that is similar to what is currently recommended. We would change your diabetes treatment based upon which group you are assigned to. But all of the medications that we would be using in the study are currently approved diabetes medications that your doctor and all medical providers are using at this time so it is nothing that is experimental or untested. So if you are randomized to the intensive blood sugar goal its very likely that you would need (7:00) more treatment because to get to a

lower blood sugar goal it often requires two oral medications, usually insulin and lots of contact with us because we will be adjusting your insulin and then frequent blood sugar monitoring so you may have to take several pills, take insulin, do finger stick testing up to 8 times a day so it can be quite involved so want to make sure you understand the commitment that would be involved if you were to be randomized to the intensive arm.

The way we measure how your diabetes management is going is by a test called a hemoglobin A1c. This test is like an average of your blood sugar over the last two to three months. If you are in the intensive treatment group the goal would be to keep your A1c less than 6% (8:03) which is what somebody without diabetes has as far as an A1c. This is much lower than what we are usually targeting in clinical practice and if you're in the standard group the goal would be to keep your A1c somewhere between 7 and 7.9 which averages out to a blood sugar of 160 if you are testing on your finger sticks. This is a little bit lower than what is usually achieved in clinical practice but we know from previous experience that bringing the A1c down from the 8 and the 9 range into the 7 range really reduces your risk of having eye, kidney, and nerve complications. But the question is if we go lower than that there is always a risk of having more of hypoglycemia, which is also known as low blood sugar so we want to try find the balance (9:02) of what's best. We know that compared to the intensive target of less than 6% the standard target of 7.5% has a little bit higher risk for some diabetes complications and these include eye disease, kidney disease and abnormal nerve function or neuropathy. Some people describe that as a burning sensation in their feet, you may know other people who've experienced that. On the other hand, we know that getting an A1c of less than 6% can increase your risk of developing serious low blood sugars and can cause some weight gain and so whether the lower A1c is better or the higher A1c is better as far as protecting against heart disease is really what we ACCORD is trying to find out. And in the standard group ACCORD will recommend treatment and take further action if your A1c goes higher than 7.9% (10:05) and if your A1c drops below 7% we may be removing some insulin or some medications so that it is in the targeted range. In the intensive group if your A1c is even slightly over 6% we will increase your treatment. So the importance of this study is really keeping a difference between the two groups because if we don't have a difference we won't be able to answer this question. So it's very important that you're willing to commit to doing everything needed to achieve the A1c targets and we'll help you along with that of course.

Depending on your initial blood pressure and cholesterol results you will be asked to participate in either the blood pressure or the lipid treatment arms of the study. We know that blood pressure treatment can help prevent heart disease, stroke, and kidney disease.

And there is some evidence that lowering blood pressure further than what's currently recommended can help prevent heart disease or stroke in people with diabetes. But we don't have any large scale studies that have ever been done to show that so that's what we want to do. If you're in the blood pressure portion of the study again you will be randomly assigned, again like the flip of a coin, to either the intensive or standard blood pressure target. Your study doctor will choose the medications that would be best for you based on side effects or any concerns that you have and we'll find the best treatment that works well for you. Again, we're using all standard, approved medications that we use in clinical practice; it's just that the blood pressure targets will be different depending on which group you are assigned to. (12:00)

In the blood lipid treatment group we know that lowering blood cholesterol can help prevent heart disease and stroke. There's some evidence that changing other blood lipids by lowering triglycerides or your blood fats and raising your HDL-cholesterol which is also known as the good cholesterol, that might prevent heart disease in people with diabetes. But we also need to test this a little more carefully. So if you are eligible for the lipid part of the study, your current medication, if you are on any, will be stopped and then we'll change you to the study medication. You'll be treated with a medication known as a "statin" and statins mainly work at lowering your bad cholesterol. And we do have a lot of evidence that patients taking statins that have diabetes really have a lower risk of heart disease so we know that's the standard practice so we definitely want to keep you on that but the question is if we add a second medication that lowers your blood fats and raises your good cholesterol, if that will give you more benefit. And so everybody will be on the statin medication, known as simvastatin, and then half of you would be assigned to the fenofibrate group, which is the medication that lowers your triglycerides and raises your HDL and half of you would be assigned to a placebo, which is a pill that does not contain any medication. But it's very important that you take either the fenofibrate or the placebo for the entire study so that in the end we'll actually know if those taking the real study drug compared to those taking the placebo had different outcomes. If, during the study, your cholesterol remains too high we'll have to adjust the dose of the simvastatin to target your cholesterol to the recommended level. (14:06) We do know that fenofibrate could possibly harm the kidney so we'll be doing frequent blood tests just to watch your kidney function. If your results are not normal then your dose of fenofibrate or placebo will be reduced or stopped and after your dose is reduced or stopped, your doctor will continue to monitor your kidney function.

So that was a lot of information. Can I ask if you have any questions about the diabetes, the blood pressure or the cholesterol arms of the study? And if not then I'll keep going.

So there is a genetic component. Genetic research will be done as part of this study and you may if you wish volunteer for the genetic portion of the study. Just because you are in the study does not mean you automatically have to be in the genetic component. (15:02) But if you wish to participate, then we will store some of your blood samples to look at some genetic analysis. And we'll talk about that in more detail a little bit further in the consent.

So the visit schedules, this is a long study, it's going to be over years and it's a long time commitment. Visits can be as frequent as every one month to as little as every four months. But you will be coming in quite often with phone calls in between. And so again we just want to make sure you feel comfortable with the idea that you're going to be in this for a long time. Depending on which group you are in, there may be more frequent or less frequent visits but in general the least would be every four months and the most would be every month. We'll do blood draws every four months for the first year and then once a year after that and they are all standard labs that we would be measuring in clinical practice and we will again share those with your own doctor.

If you are assigned to the intensive blood sugar goal, as I said you will have more frequent blood sugar testing in the clinic and the testing will range from once a month during the first four months to every two months thereafter but we will be contacting you at least monthly to check in how things are going.

If you are in the cholesterol study your blood cholesterol will be measured every four months during the first year and every year after that until the end of the study. You'll also have blood drawn every four months throughout the study to check your kidney function. If you are not in the cholesterol study you will have your cholesterol measured every year. And as part of diabetes management you will be expected to check (17:06) your own blood sugar as discussed later. All we will provide you with are the test supplies and test strips in order to do that. Some urine will be collected at the baseline visit and every two years thereafter so it can be examined for protein and creatinine which is a measure of your kidney function. And we'll also do an EKG which is a recording of the electrical activity of the heart at the first visit, at baseline and then every two years after that. And we'll do an eye exam every other year.

So you also have a one in five chance, so if there were 100 people then 20 people would be chosen to complete questionnaires about your quality and activities of life and then also about your diet and physical activity levels. So these questionnaires can take a little bit of time to fill out, about an hour. We'll ask you to complete them at the beginning of the study, at one and three years, and at the four year visit.

And there is another, sort of sub-study. A smaller portion of people may be asked to participate in a group where healthcare costs will be monitored. And then if you are admitted to the hospital, then we would ask for your permission to obtain any medical records.

There are certain medical procedures and tests that are not part of the research study that are recommended in general for people with diabetes and so it's very important that you still follow-up with these with your primary care physician or provider on at least a yearly basis. We recommend eye exams with an eye doctor, foot exams, getting vaccinations, flu shots, flu and pneumonia vaccinations, EKGs and we don't replace these with our exams. So the eye exam we conduct (19:00) is not a clinical exam, it's more of a research exam so we still ask that you follow up with your primary doctor and have your standard health assessments done every year.

During the course of the trial the central coordinating center or one of its representatives may contact you about your participation in the trial, for example you may be asked if you're having any trouble taking any of your medications and you may be asked how you're feeling or whether you've been in the hospital for any reason or where or why you were hospitalized.

So with such a long study and many treatments there are several risks of participating in the study and I want you to be aware of those. So what are the possible risks? Well, because we do not know the risks and potential harm to an unborn child we really want to make sure that you will not be becoming pregnant in this study (20:02) if you are a woman and so we ask that you use a reliable method of birth control through the study or if you're not willing to do that than we would ask that you not participate in this study. But there are several reliable methods of birth control and those are listed in the consent form here. If you are a pregnant woman you can't participate in this study and we just would require a pregnancy test at least 10 days after your period if you are sexually active and you're at the age where you could have children.

So we are also going to be doing several blood draws in this study and anytime we are drawing blood there is a risk for infection, risk for pain, and feeling light headed or faint. I'm sure most of you have had blood drawn but sometimes it can be uncomfortable. We also ask that you do finger stick measurements of your blood sugar level and again we are going to be providing the test strips and the testing supplies needed but it can be uncomfortable and when you are asked to possibly test eight times a day, that's something I just want you to keep in mind, that that's a possibility. If you are assigned to the intensive blood sugar goal there is a good chance that you'll be asked to do up to

eight times a day and then we review your glucose values and then we're able to better make adjustments. So the reason we want you to test so frequently is so we can most safely change you're diabetes treatment so that we can achieve the goal of the very low blood sugar readings without causing too much of hypoglycemia or low blood sugar. When we're talking about risks of hypoglycemia or low blood sugar, this can happen when you are doing more exercise, you're eating less and certain symptoms can occur when that happens. (22:09) Mild symptoms can include feeling hungry, anxious, dizzy, light headed sometimes you're sweating, feel very tired, you can be confused or you can have some shaking or feeling like your hearts racing, it can be a very uncomfortable feeling and since we know, especially in the intensive group you are more likely to experience this we just want you to be aware so you are not surprised. Most people who've had diabetes have experienced this in some degree but not everybody has. So if it is new to you I'd like you to know what that would feel like.

Serious hypoglycemia or low blood sugar may cause a loss of consciousness and if this occurs while you're driving or operating machinery it can really result in a terrible injury and could be life-threatening. But again, we ask that you test your blood sugars often so we can predict your patterns more and try to avoid this as much as possible. In very rare cases, hypoglycemia can be severe and require emergency treatment or hospitalization and severe low blood sugars can cause brain damage, coma and death and this can happen in any patient taking medication to lower blood sugar but it is more common in those taking insulin in the intensive treatment. So you usually juice or glucose tablets known as sugar pills can raise your blood sugar if you have those symptoms and if the low blood sugar is severe enough then sometimes it's going to require paramedics coming to the home and putting intravenous fluids or glucose into your vein (24:01) or giving you glucagon which is a medication that rapidly increases your blood sugar. But again, this risk is very small but it is a possibility. Regardless of which blood sugar treatment group you are assigned to, safety will always be a first importance when the changes in your management of your sugar are made. Based on data from previous studies it's estimated about 6 out of 100 participants will have a serious complication like a hospitalization, an emergency room visit for hypoglycemia and in the standard group about 2 participants may have that sort of a complication each year. In either group the ACCORD doctors and nurses will take to action to lessen the risk of hypoglycemia if it should occur too often or in a severe form. So that's again why frequent communication is really important. On the other hand participants in the standard group may have a somewhat higher risk of complications related to diabetes like eye, kidney disease, or abnormal nerve function (25:04) and its estimated that in the intensive group about 1 out of 100 participants will have a complication every year and the standard group about 1 ½

participants out of 100 may have such a complication every year. So again it is a small amount but it is a real risk of having these complications.

So if you are assigned to the intensive blood pressure group you may experience blood pressure that's too low and typically people can feel dizzy or light headed or feeling like they are about to faint so sitting down, moving slowly, that typically relieves these symptoms but if you experience any of these things I'd like you to let us know right away so we can adjust your treatment.

So now I'm going to talk about each of the medications that we could possibly by using in the study. Now all the medication that I will be discussing here are standard medications that we use every day in our clinical practice. And we do know that any medication has a potential risk of having an allergic reaction and if we don't treat that right away it could become life threatening. So again if you experience any side effects it's really important that you let us know right away.

The blood sugar treatments, Sulfonylureas are the first class of medications. They've been around for a very long time. They work by causing your pancreas to make more insulin. Because we're causing your pancreas to make more insulin, the most common side effect in this family is low blood sugar. We can also see some weight gain because if you have too much insulin around it can cause you to be more hungry and you can also have allergies. There are also some very rare blood cell abnormalities that can occur but we always check your blood and make sure that that's not happening. Biguanids or metformin have also been around for a long time. Metformin mostly has side effects related to your digestive tract or your stomach. So commons side effects in this class can be nausea, vomiting, diarrhea, bloating, and loss of appetite or a metallic taste in your mouth. Usually we start at a very low dose and we increase this slowly so you don't have this side effect. If it continues then we would always reduce the dose or stop the medication. And very rarely people can have a severe reaction know as lactic acidosis which is when your body fluids have too much acid in them. And it almost always occurs in people who have advanced kidney disease, liver disease, or heart failure and in those who drink a lot of alcohol so we won't put you on this medication if you have any of those conditions. And again we're measuring blood tests to look at these risks.

Another group is an oral medication called a thizaolidinediones, which is a very large word, but it's a medication call rosiglitazone. Rosiglitazone is a tablet that you take. The most common side effects of this group include retaining fluids so you can have ankle swelling and that just causes you to hold too much water and it can cause weight gain. This is a very good medication at reducing your blood sugar but with the side effect that

it can cause some swelling and some weight gain. This medication has been used in combination with insulin in research studies but then in this study we have the potential of using it with a higher dose and its possible that that could cause more fluid build-up and could worsen heart failure. Of course if you have heart failure we would not put you on this medication. Symptoms of heart failure, if you were to experience it, include feeling short of breath, having a cough, tiredness, ankle swelling or weight gain so please let us know if you do experience this. There was a report of an older medication in the same family that had caused liver problems so we do check liver function tests every once and a while just to be sure that that's not a problem, but nothing has been reported with this particular medication.

Then we talk about insulin and there's many different types of insulin. Insulin is an injection that you would take and sometimes it's a long acting insulin that lasts a whole day and sometimes it would be short acting insulins that you would take only with meals. (30:00) And the main side effect is having a low blood sugar if you take too much but we start at a very low dose and try to increase that slowly. Very rarely you can also have low potassium in the blood or an allergic reaction or a skin irritation from taking the insulin.

And the last medication family is one called Repaglinide or meglitinide. This is also a pill you would take before eating and the idea is to bring your blood sugars down after eating and common side effects include headache, upper respiratory infections, nausea, vomiting, constipation, and diarrhea. And the most serious side effect is low blood sugar. Testing your blood sugar frequently would help us figure out if you are having side effects from this.

Now there are many, many blood pressure treatments that are currently available and the one we chose for you to be on, if you are in the blood pressure arm of the study is dependent on many factors including your life style, taking it once a day versus twice a day and so we try to individualize the treatment so we get the best treatment for you. We know one medication is called an Ace Inhibitor or a Angiotensin converting Enzyme Inhibitor, common names are benazepril, Lisinopril, Ramipril, a lot of diabetic patients are on this. Potential side effects include dizziness, headache, fatigue, nausea, diarrhea, cough, rash, high potassium in the blood. Any of these blood pressure treatments can cause light headedness or dizziness if your blood pressure goes too low so again we increase the dose slowly. Rarely you can have severe reactions, swelling of the face, lips, and tongue, called angioedema but again this is rare.

Diuretics are also known as water pills and most of the side effects include muscle cramps, nausea, vomiting, diarrhea, dizziness, rash, weakness, and low blood pressure.

Low potassium can also happens so we're going to be monitoring your potassium levels, high blood sugars and then you can have some sexual function problems and gout, which is painful condition that occurs when too much acid and salt build up in the blood stream and joints.

Another class of medications are called Beta Blockers and the way they work is they slow down your heart rate. The most common side effects, because they are slowing down your heart rate, include dizziness, fatigue, stomach upset, depression, cold hands and feet, low blood pressure, changes in heart rhythm and heart rate, and a decrease in sexual function. And among people that have diabetes there are some reports that medications in this family they may hide some of these symptoms that you would get when your blood sugar goes low but not the hazards of low blood sugar so it's very important again that you test your blood sugar more often, particularly if you're on this medication.

Calcium Channel Blockers are another way of lowering blood pressure. Most frequent side effect of these are ankle or foot swelling, dizziness, flushing, palpitations, which is just sort of like a rapid heartbeat, you can also have headache, fatigue, nausea, and abdominal discomfort.

Alpha Blockers, they open up your blood vessels a little bit more and try to reduce blood pressure that way. Potential side effects in this category can be fainting, dizziness, fatigue, swelling, low blood pressure, and problems with your sexual function, heart rate changes and blood cell abnormalities.

Alpha II Receptor Blockers are another class of medication. Most of these medications have very similar side effects but the most common side effects are dizziness, headache, fatigue, diarrhea, muscular-skeletal pain. The more serious side effects are angioedema that we had mentioned, the swelling of lips, face, and tongue that can result in difficulty breathing and in rare cases, death, and severe low blood pressure. This family of drugs can also affect your kidney function so we will be doing blood tests to see if your kidneys are performing properly.

There is a medication called furosemide which is another water pill, it's called a loop diuretic, and these have side effects including low platelet counts, rash, pancreatitis which is an inflammation of the pancreas, jaundice, or yellowing of the skin or whites of the eyes indicating possible liver problems. (35:14) and serious side effects include abnormalities in the blood cells.

Reserpine is another medication in the family called Sympatholytics, and the most common side effects include dizziness, dry mouth, nausea, vomiting, nasal congestion, edema, which is a swelling in the body tissues, too much fluid in the body's tissues, stomach cramps, headache, impotence, which means difficulty with sexual function, depression, nervousness, shortness of breath, nightmares, difficulty in urinating, shaky hands and a poor appetite. These side effects have been seen in much higher doses than we would actually be using in our practice but they are listed regardless. More serious side effects include heart rhythm changes, black tarry stools, vomiting blood, slow heart rate, chest pain and low platelet counts.

The vasodilators – one medication in that family that we will be using is hydralazine and the side effects in this include headache, fast heart rate, chest pain, and palpitations or a feeling of rapid heart rate. Rare and more serious side effects include abnormalities in your blood cells and some symptoms associated with a condition called lupus, which can result in more fatigue and tiredness.

Potassium Sparing Diuretics, one is called triamterene the most common side effects include diarrhea, nausea, vomiting, gastrointestinal distress, or discomfort in your stomach, dizziness, dry mouth, itching, rash, sensitivity to light, weakness, low blood pressure, muscle cramps, blood chemical imbalances such as too much potassium, impaired kidney function, and then elevated uric acid, blood cell abnormalities and reduced folic acid stores. And there's always a risk of more serious side effects including acid in the blood and shock due to an allergic reaction to the medication. And in the beginning when we first put you on any of these medications we monitor you very closely for side effects and if there is any sense that you are experiencing any of these side effects then we will discontinue or reduce the dose.

The last medication in this blood pressure arm are called alpha blockers, carvedilol is one and the most common side effects are dizziness and fatigue. The more serious side effects include a heart rhythm disturbance, a slow heart rate, a low platelet count, and bronchospasm or tightening of the breathing airways. Alpha-beta-blockers may also hide some of the symptoms but not the hazards of low blood sugar. So those are the many medication that we could use in the blood pressure arm of the study if you were enrolled in that portion.

Now the cholesterol part of the study. Everyone that would be in the cholesterol part of the study would be on a medication called simvastatin. The common side effects in this medication include headache, dizziness, upset stomach. Rare, but more serious side-effects are muscle aches, rash and elevated liver enzymes so in the beginning of the study

when we first put you on it we will be asking you questions about any experiences with muscle aches and we'll be measuring some blood tests at the beginning and then also shortly after you start taking the medication to be sure that that's not happening.

Now if you are in the cholesterol part of the study and you are assigned to the fenofibrate group; fenofibrate is a medication that has been associated with abdominal pain, gall bladder stones, and jaundice which is yellowing of the skin or eyes indicating liver problems, It can also be associated with headache, change in taste, elevated kidney and liver tests and certain abnormalities in the blood cells. So if you are on finofibrate or the placebo we'll be measuring your liver and kidney tests.

So all of these medications, as I said, are available and are used in clinical practice (40:00) most have been used for many, many years. But we know much about how each of the individual drugs work and how they interact with other drugs, especially other treatments that will be used in the study. One medication called sulfonylurea which is a diabetes pill is not to be used with other certain drugs and so your doctor in the study will make sure that we don't have any interactions that could cause problems.

And we also know that using the cholesterol medication called statins or simvastatin and fibrates together could possibly increase your chances with problems with the liver and muscle pain and inflammation and these are very rare, but at higher doses they're more likely and so if we have to increase your cholesterol medication simvastatin to 40 mg a day your chance of side effects may be increased and so we will use caution whenever you are given a combination of simvastatin and fenofibrate. Many doctors do use this combination and we have received permission from the FDA to test this combination. Also, the accord clinic will be checking your blood to make sure the study medications are not harming your liver or your muscles and that will be done at the beginning and then at 4, 8, and 12 months and then every year after that. And if at any point you feel that you are having muscle pain or any side effects then we can always test this more frequently or on a as needed basis. And if looks like the combination of these medications is causing a problem then we may take you off of one or both of these medications.

And if you are on the lipid portion of the study and you're on Coumadin which is a blood thinner also known as warfarin your own doctor will be informed by phone and in writing that you may be on the fenofibrate because the use of fenofibrate generally means that your dose of Coumadin should be reduced so that you aren't at lower risk of having bleeds, we'll just make sure your doctor knows about that.

So what are the benefits? So we don't know if the ACCORD treatment either the standard or the intensive group or the blood pressure or the cholesterol arms of the study will actually benefit you personally, but we do know that gathering this information will help future generations and possibly your own generation just to know what's the best way to treat Type 2 diabetes and there is going to be no charge to you for any of the treatments that we use in the study or any of the testing supplies, visits or laboratory exams and your doctor will be notified of all of these results. But you will not be paid for your participation in the study but all the testing supplies and everything will be free of charge.

And what are the alternatives? Well as we're actually using medications that are used in clinic, you can have the same sort of treatment with your own primary care doctor and that's your alternative is that you would just have your diabetes and blood pressure and cholesterol managed by your own doctor including diet, exercise, weight loss all as treatments for your diabetes.

And as part of our study you would also be given an opportunity to work with our dietician and diabetes educators to do very similar things.

If you have any sort of research related injury throughout the study, it's not likely that you would suffer any major health problems by participating in the study but there's always a small risk of having serious health complications and if that should occur, treatment would be available including first aid, emergency treatment and follow-up care and they'll just be billed in the ordinary manner to your insurance company, it's not paid for by the study.

As far as confidentiality we want to protect your privacy so any information that we gather about you during the study will be treated as strictly confidential and we will be assigning you a code number if you participate in this study so there will be no name or information about you associated with your name. However, your name and Social Security and Medicare numbers will be recorded and stored centrally to help the study keep track of any illnesses you may experience and if you order free testing supplies to measure your own blood glucose you need to provide the information so that we can bill it to Medicare or any insurance you may have. (45:02) And if you don't have Medicare or other insurance then the study will cover the cost of that. And when we publish the data there will be no identifying features about you in the publication. At the end of the study, then all the forms with your name and other identifying information will be kept in a locked room for up to five years and only your study doctor or co-workers assisting the doctor will have any access to these forms. After five years, the forms will be destroyed.

Any blood, urine and tissue samples that we have taken from you during the study will be considered donated by you to medical research. And these materials may also be provided to the National Heart Lung and Blood institute at the end of the study, again, with no personal identifying information but it may be shared with other scientists who meet the requirements so that we can learn more about diabetes and related problems. Drug companies that have contributed drugs, and in some cases money, to the ACCORD study will also be provided study data but again with no personal identifying information.

It's important for you to know that ACCORD has been granted a Certificate of Confidentiality form the US Government to make sure that we protect your privacy. This means that the ACCORD researchers cannot be forced to tell anyone that's not connected with the study about your participation. And this includes courts and police. The researchers will only release information if you request it yourself.

There are some limits to the researcher's ability to maintain your confidentiality. If we learn that keeping information private would immediately put you in danger, or put someone else we know in danger, then we will have to tell the appropriate agencies to protect you or the other person.

So your participation I this study is completely voluntary. You may choose at any time in the study to withdraw or end your participation with us and there will be no penalty or loss of any benefits to you if you decide you don't want to participate in this study anymore and your study doctor also has the right to stop your participation in the study at any time if they feel necessary. This could be because you had an unexpected reaction, or if you have failed to follow instructions, or because the whole study had been stopped early.

So any new information that we gather about the study or anything that may affect your health, welfare, or willingness to stay in the ACCORD study will be shared with you and results of your lab tests and clinical measurements will be provided to you to share with your own physician.

Now I'd like to ask you what question you have for me, I'd be happy to go through any areas that are not clear to you, just so that we're sure that you understand what is expected of you. I'd like to you to explain in your own words what we're asking you to do.

I do want to go through some contact phone numbers that if you have at any point a question that you would feel more comfortable with talking with somebody that's not

involved in the study we have a Fairview Research helpline with the contact information below and if you'd like to talk to our main study investigator, Dr. Seaquist, her contact information is here as well.

Now I'll just briefly talk about the genetic studies. Again, genetic studies are an extra part of the study. You don't have to participate in the genetic study to be part of the main ACCORD trial. One of the goals in ACCORD is to examine your genetic material and its relationship to the effects of the treatments. If you volunteer to participate in the genetic studies you'll be asked for a sample of blood, about 1 teaspoon to obtain DNA from your blood cells, DNA is just the genetic material in your blood cells. What will happen to the DNA samples? Well, we'll examine directly your DNA or create a living tissue sample or a cell line and this gives researchers an unlimited supply of DNA that they can use in the future without having to draw more blood from you. And it's not a human clone of you but it's just more cells from that small sample you give us (50:03) to begin with.

Will we share the DNA with any other institutions? With your permission, the ACCORD Central Laboratory may share DAN samples with researchers participating in the ACCORD study. If you give permission, samples may also be shared with other research laboratories studying the genetics of type 2 diabetes and the development of heart and blood vessel diseases, other major diseases, health conditions, or risk factors. The scientists from these laboratories would be given the DAN and there is no information about you in there.

And how will they be used in the future, these samples? Information gained from research on your cell line may be used to develop new ways to detect or treat major diseases.

And how will we keep this genetic information private? Only the ACCORD study data manager will have access. No other individual, including your spouse, parents, children, physician or employer will have access to the stored sample or information gained from your stored sample. At the end of the study, your samples may be provided to other investigators under certain conditions, without any personal identifying information.

How long will the DNA samples be kept? Your sample may be kept until it is no longer of scientific value. If, at any time during the study, you decide that you do not wish to have your DNA sample stored any longer, the sample will be destroyed.

Who owns the sample? By checking "yes at the end of this document, you volunteer to provide genetic samples for medical research purposes. Your cell line or DNA will not be

sold to anyone or to institutions or companies for financial gain or commercial profit without your consent. However, neither you nor your heirs, meaning possibly your children or spouse will receive any money from any discoveries or inventions made using the information and/or specimens you provide.

Will you receive study results of research involving your samples? This is not a clinical test so it's not used to give you an specific information about your own health or genes so you will not be informed of any of the results of the research performed on your genetic blood sample. Although a genetic test may be developed after a study of samples in the ACCORD study. If there is any new information about genetic testing for type 2 diabetes and its relationship to heart and blood vessel diseases or other health conditions, you will be informed by your study doctor if this information may be important to you or your family. And there is no cost to you for any of this. So if you decide you would like to participate in the genetic portion you have three options.

One is to check 'Yes, I agree to participate in the genetic portion of ACCORD and to allow a living tissue sample to be developed for future genetic studies" or you have the option of just agreeing to participate in the genetic portion but not having a cell line developed or you can decide you do not want to participate in the genetic portion.

And then you can also choose which conditions you would like your genetic sample to be studied if you decide you want to participate so you can chose any major disease or health condition or risk factors or you can choose only for genes related to diabetes, blood pressure, blood cholesterol abnormalities, heart disease, other cardiovascular diseases, kidney disease or other risk factors for heart disease and then if you agree to participate in the genetic portion then we want you to check one of the following involving the investigators who will have access to it. So you can choose to allow the genetic samples to be used for research by the ACCORD investigators as well as by other researchers who meet the standards and procedures for the National Heart Lung and Blood Institute or you can decide you would only like your genetic samples to be used only for research by ACCORD investigators.

So that was a lot of information and I know you probably have more questions regarding this. I would be happy to answer any of them. Now that we've reviewed the consent form together I'd like you to take some time to actually think about it before signing. This is a big commitment on your part and on our part as well and I want to be sure you feel comfortable with the study before you actually enroll in it so I'd be happy to take any questions that you have and if you could explain to me what you think we are asking you to do then we can be sure you understand the study completely.

Appendix V

Original ACCORD Consent Form Spanish

Formulario de Consentimiento del 27 de mayo de 2005

Action to Control Cardiovascular Risk in Diabetes (ACCORD)

Investigadora Principal: Elizabeth Seaquist MD, Departamento de Medicina en la Universidad de Minnesota

Esta invitado a participar en el estudio de investigación por nombre Action to Control Cardiovascular Risk in Diabetes (ACCORD) (tomando acción para controlar el riesgo de enfermedades cardiovasculares en la diabetes). Este estudio es respaldado por National Heart, Lung and Blood Institute (NHLBI) (el instituto nacional del corazón, pulmón y sangre (financiado por el gobierno federal)). Estamos invitándole a participar en ACCORD porque usted tiene diabetes tipo 2, junto con otros factores que aumentan el riesgo de que tenga en el futuro o que ya tiene cardiopatía (enfermedad del corazón) o apoplejía (derrame cerebral).

La investigadora mencionada es la encargada de este estudio. También hay otros médicos profesionales que podrán ayudar o actuar por la doctora Seaquist.

Los detalles de este estudio se describen a continuación. Es importante que usted entienda la información para decidir participar de manera libre e informada, si desea participar. Recibirá una copia de este formulario de consentimiento. Si tiene preguntas acerca de este estudio, diríjalas en cualquier momento a la investigadora antes nombrada o a sus asistentes.

Información previa:

¿Cuál es el propósito del estudio y cuánto se demorará? Diabetes tipo 2 es el más común en Norte América. Individuos con diabetes tipo 2 corren un riesgo más alto que tengan cardiopatía o apoplejía. El propósito del estudio ACCORD es determinar los mejores tratamientos para reducir el riesgo de apoplejía o cardiopatía en personas con diabetes tipo 2.

El estudio responderá tres preguntas. En diabetes, el nivel de azúcar en la sangre es demasiado alta. La primera pregunta determina cuando el azúcar en la sangre se va por debajo de la práctica general, en comparación a una meta que suelen ser normal. Muchos pacientes diabéticos tienen hipertensión. Entonces, la siguiente pregunta determina cuando la presión de la sangre se va por debajo de la práctica general, en comparación a una meta que suelen ser normal. Muchos de ellos también tienen problemas con los lípidos de la sangre (como el colesterol, componentes en la sangre tipo grasosos). Entonces, la tercera pregunta determina los efectos del tratamiento de varios componentes de los lípidos de la sangre (lipemia), en comparación del tratamiento de un solo componente. A continuación se describe cada pregunta con más detalle.

Su participación durará hasta junio de 2009. De cualquier manera, el resultado del estudio será revisado con objetivo primordialidad para determinar si es necesario terminarlo antes de la fecha ya mencionado. La mayoría de los participantes estarán en el estudio de ACCORD entre 5 ½ y 8 ½ años.

Tendremos 10.000 participantes en total aproximadamente de 70 clínicas de los Estados Unidos y Canadá. Alrededor de 250 pacientes de la clínica de University of Minnesota participaran en este estudio. ACCORD recluyo como 1.200 participantes durante el piloto Vanguardia, porción del estudio 2001 y todavía están siendo tratados y seguidos

Procedimientos:

¿Qué ocurrirá si participa en este estudio? Las citas iniciales lo conducirán a determinar si usted califica para participar en este estudio. Estas se llamaran citas de "exámenes de exploración". Si califica,

revisarán el historial médico, la presión en la sangre, los niveles de azúcar y colesterol en la sangre. El examen físico será breve tomaran sangre en un tubo (como dos cucharaditas) para el análisis de creatinina (la medida de la función de los riñones), lípidos y la función del hígado. También tomarán una muestra de orina para el análisis de proteína.

Si usted califica para el estudio y participará como voluntario el doctor del estudio tratará la azúcar y presión en la sangre o los lípidos en la sangre de acuerdo al protocolo del estudio ACCORD. Su doctor y usted aún son responsables de las otras partes del cuidado general de la diabetes como medidas preventivas del cuidado de los pies y los ojos. Si no está en el grupo de ACCORD que se trata de hipertensión, su médico profesional aun es responsable del cuidado de su tratamiento. Si no está en el grupo de ACCORD que se trata de lipemia, su médico profesional aun es responsable del tratamiento de los lípidos en la sangre (tales como colesterol). En suma, no deje de consultar con el médico de otros cuidados de salud.

Grupo de tratamiento del azúcar en la sangre. Si usted califica y es consciente de participar en este estudio entonces será seleccionado (como lanzamiento de la moneda) a uno de dos metas de azúcar en la sangre. La meta "intensiva" es tener la azúcar en la sangre más bajo de lo recomendado. La meta "objetivo primordial" es tener la azúcar en la sangre similar a lo recomendado. Su tratamiento de diabetes si tiene será cambiado al tratamiento del estudio según su asignación de grupo. Los tratamientos de diabetes (oral e/o insulina como se lo pidan) aprobados y disponibles serán utilizados en el estudio.

Si le toca usted estar en la meta intensiva de la azúcar en la sangre, es probable que usted necesitara una o más de lo siguiente: a) a lo mínimo 2 medicamentos oral; b) 3 o más inyecciones de insulina al día; c) una frecuencia de auto-ajuste de insulina; y d) una frecuencia de chequeo en el hogar de la glucosita. Esto significa que tendrá que tomar varias píldoras, inyectarse con una aguja pequeña la insulina, y picarse el dedo hasta ocho veces al día para checarse el azúcar en la sangre.

El grado de control del azúcar en la sangre es medida mejor por un análisis que se llama hemoglobina A1c. Este examen da un resumen de los datos de la azúcar en la sangre por los últimos 2 a 3 meces. Si le toca estar en el grupo intensivo del tratamiento de la azúcar en la sangre, la meta será mantener su hemoglobina A1c a menos de 6,0% que viene siendo como 115 mg/dl o 6,4 mmol/L de azúcar en la sangre. Este nivel es mucho más bajo de la práctica general. Si le toca estar en el grupo de tratamiento objetivo primordial, la meta será mantener su hemoglobina A1c entre 7,0% y 7,9% aproximadamente 7,5% (promedio 160 mg/dl o 8,9 mmol/L de azúcar en la sangre). Este nivel también es más bajo de la práctica general. Se ha demostrado cuando se baja el nivel de la hemoglobina A1c a esta meta las complicaciones de diabetes como la enfermedad de los ojos o los riñones es reducida. Su medicamento de la diabetes será moderado si necesita más o menos como indiquen los doctores de este estudio para llegar a esas metas en una manera saludable.
En comparación a la meta intensiva de hemoglobina A1c menos de 6,0 %, la meta objetivo primordial de 7,5 % hemoglobina A1c tiene un poco más de riesgo de complicaciones de diabetes. Esto incluye la enfermedad de los ojos, retinopatía, enfermedad de los riñones, nefropatía, y la función anormal de los nervios, neuropatía. En el otro lado, un nivel de hemoglobina A1c menos de 6,0% aumentara el riesgo que desarrollara reacciones serias de bajos niveles de azúcar en la sangre, hipoglicemia, y subir de peso. Aun no se sabe que si hay más o menos protección en contra de las enfermedades cardiovasculares como ataque del corazón o apoplejía cuando se baja el nivel de hemoglobina A1c. Esto es lo que ACCORD está tratando de encontrar.

En el grupo objetivo primordial, ACCORD tomara acción y recomendara un tratamiento para bajar el azúcar en la sangre si su nivel de hemoglobina A1c sube más de 7,9%. Si la hemoglobina A1c se baja más de 7,0% y está tomando insulina o secretagogue como glimepiride o repaglinide, tendremos que reducir su tratamiento de diabetes para subir su nivel arriba de 7,0%. Si su nivel de hemoglobina A1c sube un poco más de 6,0 %, en el grupo intensivo su tratamiento será aumentado.

También le preguntaremos que participe en la parte del estudio sobre la presión de la sangre o colesterol, con respecto a los resultados que le tomamos inicialmente. Tendrá que estar en uno (según su calificación) de los dos para tomar completa ventaja de ACCORD.

El grupo de tratamiento de la presión de la sangre. Cuando la alta presión de la sangre se baja puede prevenir enfermedad del corazón, derrame cerebral, y enfermedad del riñón. Hay evidencia que cuando bajamos la alta presión más de lo que suele ser normal posiblemente podrá prevenir enfermedad del corazón y derrame cerebral en personas con diabetes. Esta posibilidad necesita ser analizada en un estudio como este.

Si usted califica para esta porción del estudio, entonces será seleccionado (como en una lanzamiento de la moneda) para una de dos metas específicas de la presión en la sangre. La meta "intensiva" es de subyugar el nivel de la presión en la sangre cual ya es aprobado de reducir la enfermedad del corazón y apoplejía. La meta "objetivo primordial" es de mantener el nivel de la presión en la sangre cual ya es aprobado de reducir la enfermedad. Los doctores de este estudio indicaran los medicamentos que ellos sienten ser mejor para tratar la presión de su sangre. Entonces su medicamento ahora de la presión de la sangre será igual o cambiado. Si aún no alcanza la meta de la presión en su sangre, entonces el doctor cambiara su tratamiento hasta que llegue a la meta indicada.

El grupo de tratamiento de los lípidos en la sangre. Cuando el colesterol de la sangre es reducida puede prevenir enfermedad del corazón y derrame cerebral. También hay evidencia que cuando reducimos otros lípidos de la sangre como triglicéridos, un tipo de grasa en la sangre y elevando el colesterol HDL conocido como el colesterol bueno podrá prevenir enfermedad en el corazón en pacientes con diabetes. Esta posibilidad necesita ser analizada en un estudio como este.

Si usted es seleccionado en participar en el estudio de lípidos en la sangre entonces su medicamento de colesterol si tiene alguna será cambiado a la de este estudio. Este tratamiento para reducir el colesterol se conoce como "statin." **ACCORD usara la statin por nombre simvastatin.**

La dosis de simvastatin que usted usara dependerá de su historial médico. Si usted ha tenido ataque cardiaco, derrame cerebral, operación del corazón, operación de las arterias que viene sido las venas sanguinas, o angina como dolor en el corazón con cambios en un electrocardiograma (EKG o ECG), usted empezará con 40 mg de simvastatin. Si usted no ha tenido de ellas entonces recibirá 20 mg de simvastatin.

No poniendo importancia a la dosis de simastatin, usted será seleccionado (como en una lanzamiento de la moneda) a tomar un medicamento por nombre fibrate que baja los triglicéridos y eleva el colesterol HDL o el placebo que no consiste de medicina. El fibrate utilizada en ACCORD se llama fenofibrate. Ni usted y su doctor sabrán cual tratamiento ya sea el fibrate o el placebo usted recibirá. Por razones médicas si es necesario saber cuál está tomando entonces será disponible.

Si usted empieza ACCORD con la dosis de 20 mg de simvastatin y sus niveles de colesterol permanecen **más alto que el nivel recomendado, o si usted llega tener un ataque de corazón, derrame cerebral, operación del corazón, operación de las arterias que viene sido las venas sanguinas, o angina como dolor en el corazón con cambios en un electrocardiograma (EKG o ECG) durante el estudio,** entonces la dosis de simvastatin será aumentada a 40 mg por día. Si su nivel de colesterol permanece muy alta sin el resultado del tratamiento de la dosis de simvastatin ya aumentada usted terminara de tomar el medicamento y será enviado a su doctor familiar para obtener el tratamiento apropiado para reducir su nivel de colesterol.

Fenofirate tiene la posibilidad de dañar los riñones. Análisis de la sangre serán con frecuencia para evaluar la función de los riñones. Si los resultado no son normal entonces la dosis de fenobirate o el placebo cual quiera de los dos será reducido o terminado. Después que la dosis es reducido o terminado su continuara en evaluar la función de los riñones.

Componente genético. Un estudio genético será llevado acabo como parte de este estudio. Usted puede decidir voluntariamente en participar para esta porción del estudio. Si está de acuerdo entonces su sangre será almacenada para el análisis genético de ADN. La porción genética de ACCORD se describe con más detalle a continuación. Usted no necesita estar de acuerdo en participar en el estudio genético para poder estar en el estudio principal de ACCORD.

Las medidas y citas. Si usted califica para ACCORD y esta seleccionado en el grupo "objetivo primordial" de glucosa de sangre y uno de ambos que siguen: el tratamiento de lípidos o el grupo "objetivo primordial" de la presión de la sangre; tendrá que hacer citas en la clínica después de un mes, cuatro meses, y las que seguirán después de la última cita serán cada cuatro meses todo durante el tratamiento del estudio. Si usted está seleccionado en los otros grupos entonces tendrá que hacer citas cada mes por los primeros cuatro meses del estudio después de la última cita serán citas de cada dos meses hasta el final del estudio.

En cada cita su salud será evaluada y usted junto con su doctor, enfermera(o) o el personal del estudio platicaran sobre cualquier síntoma que usted siente. Tomaran su peso, la presión de la sangre, la frecuencia cardíaco, y revisaran los medicamentos para asegurar que los están tomando correctamente. Recibirán recomendaciones de nutrición y actividad física con instrucción como seguirlas. En adición de las citas objetivo primordiales, un miembro del equipo encargado del estudio de ACCORD lo llamara por teléfono en medio de ellas para determinar cómo se siente ya sella sí o no necesita más acción para controlar los niveles de la azúcar en la sangre o presión de la sangre.

Tomaran cada cuatro meses por el primer año y después anualmente muestras de sangre hasta cinco cucharadas. Los análisis serán para el azúcar en la sangre, potasio, función del riñón y función del hígado. Le pidieran tomar con su permiso especímenes de sangre y orina para almacenarlas para futuros estudios no-genéticos. También tendrá que asistir citas adicionales ocasionalmente para tomar muestras de sangre para evaluar la seguridad de los tratamientos.

Si usted es seleccionado participar en el grupo "intensivo" del azúcar en la sangre tendrá análisis de la azúcar en la sangre con más frecuencia en la clínica. Estos análisis serán mensuales por los primeros cuatro meses y después cada dos meses. Si usted es seleccionado participar en el estudio de colesterol, tomaran análisis cada cuatro meses durante el primer año y después anual hasta el final del estudio. También tomaran cada cuatro meses una muestra de sangre durante el estudio para evaluar la función

del riñón. Si no está en el estudio de colesterol, entonces harán un análisis de su colesterol cada año. Como parte de controlar su diabetes usted tendrá que checar su sangre como se describe abajo. Tomaran una muestra de orina en la cita línea base y cada dos años después para evaluar la proteína en la orina y creatinina una medida de la función del riñón. También tendrá un electrocardiograma una grabación de la actividad electrónica del corazón por nombre CCG o EKG en la cita línea base y cada dos meses después. Un examen de la vista minucioso cada otro año.

Uno persona entre cinco serán seleccionado llenar un cuestionario con respeto a la calidad de vida y sus actividades, su dieta y los niveles de actividad física. Estos cuestionarios se le darán al principio del estudio, durante el 1er y 3er año, por último en la cuarta visita del año. Estos cuestionarios tomaran una hora de su tiempo. En adición podrá ser seleccionado en participar en otro grupo donde revisaran los costos médicos y le preguntaran por su permiso para obtener los datos cuando este en el hospital.

Hay procedimientos médicos recomendados para personas con diabetes que no están en este estudio. Los procedimientos consiste del examen ocular anual por optalmologista, examen anual de los pies, vacunas anuales de pneumococcal y gripe; y electrocardiograma ECG's o EKG's.l examen ocular del estudio no remplaza el examen del especialista de los ojos como el optalmologista quien especializa en el diagnóstico y tratamiento de las enfermedades oculares.

Durante el curso del tratamiento, nuestro Centro de Coordinación en Wake Forest University School of Medicine (escuela de medicina) o los representantes le llamaran sobre su participación en este estudio. Le preguntaran por ejemplo si tiene problemas tomando su medicamento. También le preguntaran como se siente y si a estado, por cual razón ha estado y donde estuvo en el hospital.

RIESGOS PROBABLES POR PARTICIPAR EN EL ESTUDIO DE ACCORD:

¿Cuáles son los riesgos probables e incomodidades? Como no se sabe los riesgos o peligro para un feto, mujeres con actividad sexual de alto potencial de maternidad, deben usar un método anticonceptivo más seguro durante la participación de este estudio. El método considerado confiable es abstinencia no tener relaciones sexuales, conceptivos orales como la pastilla, dispositivo intrauterino (IUD), DepProvera, Norplant, ligación de las trompas (cuando las trompas son ligadas) o vasectomía del conjugue que tenga confirmación de seminograma negativo, o en una relación monógamos como una persona del mismo sexo. Un método menos confiable pero aceptable es el uso cuidadoso de condones e/o espuma o gel espermicida con un diafragma cervical, capa cervical o esponja. Le animanos que platique este caso con su doctor si tiene preguntas.

Si usted está embarazada no puede participar en este estudio. Como algunos métodos de contraconceptivos no son 100 % confiable, se necesita un resultado negativo de embarazo del análisis a lo mínimo 10 días después de su periodo menstrual normal si usted es una mujer con actividad sexual de alto potencial de maternidad.

Este estudio requiere muchas veces de muestras de sangre de la vena en su brazo durante del estudio. Al sacar la sangre puede resultar en dolor en el punto de pinchazo, sentirse desmallado, irritación de la vena, y moretón o sangrar en la área de la inyección. También una mínima posibilidad de infección en el área de inyección. Las citas del estudio, procedimientos, y resultados del laboratorio llegaran hacer más de lo que su situación médica generalmente requiere pero aún son de suma importancia para el estudio.

Este estudio requiere análisis del nivel del azúcar en la sangre diario de pinchazo en el dedo. Es probable que antes de estar en este estudio usted tenga experiencia en el pinchazo en el dedo propio. Tiene que chequear el azúcar en la sangre diariamente porque es de suma importancia para el estudio mantener la meta de los niveles del azúcar en la sangre seleccionada para usted. Si le toca estar en la meta intensivo de la azúcar en la sangre tiene una alta probabilidad que le pregunte que haga hasta ocho pinchazos en el dedo diarios para corregir el azúcar en la sangre. El personal de la clínica revisara los resultados de los chequeos de la azúcar en la sangre y serán utilizado para componer su plan de tratamiento. El personal de la clínica u otros trabajando por ACCORD le llamaran para discutir los resultados de la azúcar en la sangre.

Cuando las personas con diabetes reciben tratamiento de la azúcar en la sangre a veces puede causar que la azúcar en la sangre sea demasiado baja. Esta condición por nombre hipoglicemia es resultado cuando cambian la dieta, ejercicio o medicamento. Los síntomas son generalmente suave pero a veces más serio.

Los síntomas de hipoglicemia incluyen hambre, ansiedad, mareado. A veces hay sudor, cansancio o poca confusión, temblores (como sacudiendo) o palpitaciones cuando siente los latidos de su corazón en el pecho. Hipoglicemia puede causar le pérdida de consciencia. Si esto ocurre mientras está conduciendo mecanismo de operación como un carro, puede resultar en una herida o hasta peligro de vida.

En casos raros, hipoglicemia es grave y requiere tratamiento de emergencia o hasta quedarse en el hospital. Hipoglicemia grave causa daño cerebral, coma o muerte. Hipoglicemia grave ocurre en pacientes tomado medicamento para reducir la azúcar en la sangre. Hay más oportunidad que esto ocurra en los que están recibiendo tratamiento de insulina para alcanzar la mete de glucosa bajo como los que están en el grupo intensivo de este estudio.

Una bebida que contiene azúcar como un jugo de fruta generalmente alivia los síntomas más leves. Le darán pastillas de azúcar para elevar el azúcar en la sangre si tiene síntomas. Medicamentos son necesarios para tratar hipoglicemia grave. El tratamiento a través de las venas incluye líquidos o inyecciones de glucagón un medicamento que rápidamente eleva la azúcar en la sangre.

Sin tomar en cuenta cuales de los grupos de tratamiento esta seleccionado, su seguridad será de mayor importancia cuando cambios en su control de niveles de azúcar han sido hechos. Basado en estudios previos la estimación en el grupo intensivo es que seis de 100 participantes tendrán complicaciones graves como estar en el hospital o ir a la sala de emergencia por hipoglicemia cada año. En el grupo "estándar" solo dos participantes tendrán una complicación cada año. En ambos grupos los doctores y enfermeras de ACCORD tomar acción para reducir el riesgo de hipoglicemia si ocurre seguido o gravemente. Al contrario los participantes del grupo "estándar" tendrán un riesgo más alto de complicaciones cada año relacionado a diabetes como enfermedad de los ojos o riñón o función anormal de los nervios. La estimación de complicaciones cada ano en el grupo intensivo es uno de 100 participantes. En el grupo "estándar" será 1,5 participantes que se presenten con esas complicaciones cada año.

Si es seleccionado estar en el grupo intensivo de la presión de la sangre puede llegar a tener presión de la sangre demasiado baja. Síntomas leves de baja presión de la sangre como sentirse mareado o menos seguido pero más grave es como mareado, fatigado, o desmayo. Estar sentado o acostado trae alivio más seguido a estos síntomas. Debe avisarle al doctor o enfermera de su clínica si llega tener estos

síntomas. El personal de la clínica lo vigilaran para reducir su chanca de presión de la sangre demasiado baja.

¿Cuáles son los efectos secundarios de los medicamentos en este estudio? Todas tienen el riesgo de reacción de alergia y si no es controlada rápidamente puede poner en peligro su vida.

Puede llegar a tener efectos secundarios de las medicinas específicas seleccionadas como el tratamiento. Los medicamentos utilizados por ACCORD están a continuación. Medicamentos adicionales son seleccionados en el futuro. El personal de ACCORD le explicara cuando le lleguen a dar nuevas medicinas.

Lo siguiente describe los efectos secundarios de las clases de medicamentos. Los doctores saben cómo controlar esos efectos.

Tratamientos de la presión de la sangre

Sulfonylureas [glimepiride]: Los efectos secundarios en esta familia de medicinas más común incluye hipoglicemia (poca azúcar en la sangre), subir de peso y alergias. Las anormalidades de las células sanguinas casi nunca ocurrirán. El doctor tiene maneras de controlar las anormalidades de las células sanguinas.

Biguanides [metiformin]: Efectos secundarios de esta clase de droga incluye nausea, vómito, diarrea, hinchazón del estómago, falta de apetito o como que la boca sabe a metal. Estos generalmente se mejoran después de primeras semanas del tratamiento. Si termina el tratamiento entonces los efectos secundarios desaparecen en uno o dos días. Es rara la vez cuando una persona tiene una reacción grave como láctico acidosis que viene siendo una condición que ocurre cuando los líquidos y tejidos del cuerpo tienen mucho acido. Láctico acidosis casi siempre ocurre en personas con enfermedad avanzada de riñón, hígado o insuficiencia cardiaca y en los que beben alcohol demasiado. Tomaremos mucho esfuerzo en evitar de utilizar esta droga con las personas que tienen estas condiciones.

Thiazolidinediones (TZDs) [rosiglitazone, pioglitazone]: Los efectos secundarios relacionados con este grupo de medicinas incluye retener el líquido una condición que ocurre cuando el cuerpo retiene demasiada agua y subir de peso. Aunque la dosis de 4 mg/día de rosiglitazone el TZD utilizado en ACCORD es la única dosis que ha sido aprobada por EEUU FDA para uso con insulina, dosis de rosiglitazone más altas que le pueden dar están combinadas con insulina en la práctica médica. El uso de estas drogas como rosiglitazone juntas con insulina pueden causar la retención de líquido que puede llegar a insuficiencia cardiaca o empeorar la. Insuficiencia cardiaca es una inhabilidad de bombear suficiente sangre a través del cuerpo. Los síntomas de insuficiencia cardiaca incluyen falta de aliento, toser, fatigado, cansancio, hinchazón del tibio, o subir de peso. Si el doctor le receta insulina junto con rosiglitazone, lo revisaran por esos síntomas más seguidos para que el medicamento pueda ser ajustado si es necesario o terminar de tomarlo.

Aunque no hay ningún informe de dificultad del hígado con el uso de rosiglitazone, una medicina relacionada fue tachada de la marqueta por causa de reacciones raras pero graves del hígado. Entonces si usted necesita este medicamento, tendrán análisis de sangre buscando problemas del hígado cada dos meses por el primer año después que empieza el medicamento y cada año después.

Insulina [varios cortos-, inter-mediantes- o duraderas/long acting, incluyendo Aspart and glargine]: Los efectos relacionado con el uso de insulina incluye: poca azúcar en la sangre, poco potasio en la sangre, alergias o cambios de la piel.

Meglitindides [Repaglinide]: Efectos secundarios común incluye dolor de cabeza, infecciones del respiratorio, nausea, vomito, constipación, y diarrea. El efecto secundario grave es hipoglicemia.

Alpha-glucosidase inhibidor [acarbose]: Los efectos secundarios incluye flatulencia (aire en el estómago) y dolor estomacal. Estos son típicamente leve a moderado en severidad pero típicamente el tiempo vence la frecuencia e intensidad. Es rara la vez que este medicamento puede causar reacciones de la piel, hepatitis e/o ictericia; esto es cuando la piel y lo blanco de los ojos son color amarrillo cual significa que hay una posibilidad de problema del hígado.

Tratamientos para la presión de la sangre arterial (arteries in the blood)

Enzima Convertidora de Angiotensina Inhibidores ACE (1) [benazepril, lisinopril, ramiril]: Los efectos secundarios potenciales asociados con este tipo de medicamento incluyen: mareo, dolor de cabeza, fatiga, náuseas, diarrea, tos, sarpullido en la piel, niveles altos de potasio en la sangre, presión arterial baja al ponerse de pie, daño a la función renal y casi raro el daño angioedema (hinchazón de la cara, los labios y la lengua que pueden causar dificultad para respirar o en casos raros hasta la muerte).

Diuréticos [clortalidona, hidroclorotiazida]: Los posibles efectos secundarios asociados con este tipo de medicamento también conocido como "píldoras de agua" incluyen: calambres musculares, náuseas, vómitos, diarrea, mareo, sarpullido en la piel, debilidad, presión sanguínea baja, bajo nivel de potasio, nivel alta de azúcar en la sangre, parcial o total falta de capacidad para llevar a cabo la función sexual y la gota (una condición conjunta dolorosa que ocurre cuando demasiado ácido y sal se acumulan en el torrente sanguíneo y coyunturas).

Los Bloqueadores Beta [metoprolol]: Los efectos secundarios más comunes asociados con este grupo de medicamentos incluyen: mareo, fatiga, malestar estomacal, depresión, manos y pies fríos, presión arterial baja, los cambios en el ritmo del corazón y la frecuencia cardíaca y disminución de la función sexual. Los betabloqueantes también pueden ocultar algunos de los síntomas, pero no los riesgos de bajo nivel de azúcar en la sangre... **si usted comienza a tomar estos medicamentos, no debe dejar de tomarlos sin hablar con su médico del estudio primero.**

Bloqueadores de Canales de Calcio [isradpine, diltiazem, amlodipina, **nifedipina**]: Los más frecuente efectos secundarios asociados con este grupo de medicamentos son: hinchazón del tobillo o pie, mareos, sofocado, palpitaciones (conociendo su latido), dolor de cabeza, fatiga, náuseas y malestar abdominal. De vez en cuando, hipotensión severa (presión arterial anormalmente baja) puede ocurre al iniciar estos medicamentos o cuando ajustan su dosis. **En raras ocasiones, el aumento de la angina de pecho (dolor de pecho) y los infartos de miocardio (ataques al corazón) pueden ocurrir en personas con enfermedad coronaria severa. Cuando se combina con un bloqueador beta, la nifedipina mediación puede causar insuficiencia cardíaca congestiva (una habilidad disminución de bombear suficiente sangre a través del cuerpo), que puede ser grave, pero es muy raro.**

Bloqueadores Alfa [terazosina]: Los efectos secundarios potenciales asociados con esta categoría incluyen: desmayos, mareos, fatiga, hinchazón, presión arterial baja, la falta parcial o total de la

capacidad de realizar la función sexual, cambios en el ritmo del corazón y ciertos trastornos en las células de la sangre.

Diurético Loop [furosemida]: Los efectos secundarios raros son como la trombocitopenia (recuento bajo de plaquetas), sarpullido en la piel, pancreatitis (inflamación del páncreas), ictericia (coloración amarillenta de la piel o la parte blanca de los ojos) que indica posibles problemas del hígado. Los efectos secundarios graves incluyen anormalidades en las células sanguíneas.

Simpatolíticos [reserpina]: Los efectos secundarios más comunes incluyen mareos, boca seca, náuseas, vómitos, congestión nasal, edema periférico (exceso de líquido en los tejidos del cuerpo), calambres de estómago, dolor de cabeza, impotencia, depresión, nerviosismo, falta de aliento, pesadillas, dificultad para orinar, manos temblorosas, y anorexia (falta de apetito). Los efectos secundarios más severos incluye dysrhythmias (anormal ritmo del corazón), heces negras, hematemesis (vómitos de sangre) bradicardia (ritmo cardíaco lento) dolor en el pecho, y la trombocitopenia (recuento bajo de plaquetas).

Vasodilatadores [hidralazina]: Los efectos secundarios incluyen dolor de cabeza, taquicardia (frecuencia cardíaca rápida), angina (dolor de pecho), y palpitaciones. Raro pero los efectos secundarios más graves incluyen anormalidades en las células sanguíneas y síndrome similar al lupus.

Diuréticos de Potasio Escazo [triamterencio]: Los efectos secundarios más comunes son diarrea, náuseas, vómitos, malestar gastrointestinal, mareos, boca seca, prurito (picor), sarpullido en la piel, sensibilidad a la luz, debilidad, hipotensión, calambres musculares, los desequilibrios químicos en la sangre (tales como el exceso de potasio), función renal disminuido, ácido úrico elevado, anomalías de las células de la sangre y la reducción de almacenamiento de ácido fólico. Más graves efectos secundarios posibles incluyen el aumento de ácido en la sangre y el shock debido a una reacción alérgica a la medicación.

Bloqueadores Alfa-beta [carvedilol]: Los efectos secundarios más comunes son mareo y fatiga. Los efectos secundarios más graves incluyen bloqueo AV (un ritmo perturbación del corazón), bradicardia (ritmo cardíaco lento), trombocitopenia (recuento bajo de plaquetas) y broncoespasmo (cuando no se abren las vías respiratorias para respirar). Bloqueadores alfa-beta también pueden ocultar algunos de los síntomas, pero no los riesgos de bajo nivel de azúcar en la sangre.

<u>Tratamientos de lípidos</u>

HMG-CoA reductasa (manchas) [simvastatina]: Los efectos secundarios comunes asociados con esta clase de medicamentos colesterol reductores incluyen: dolor de cabeza, mareos, malestar estomacal. Efectos secundarios raros, pero más graves son dolor muscular, sarpullido en la piel y enzimas hepáticas elevadas (que indican posibles problemas en el hígado) en la sangre. (También, vea 'Interacciones Medicamentosas' a continuación.)

Los fibratos [fenofibrato]: Los efectos secundarios potenciales asociados a estos medicamentos incluyen: dolor abdominal, piedras en la vesícula biliar, ictericia (coloración amarillenta de la piel y / o blanco de los ojos que indican posibles problemas en el hígado), dolor de cabeza, alteración del gusto, el hígado elevada y pruebas de función renal y ciertos anormalidades en las células sanguíneas. Su médico del estudio tiene maneras de manejar estas anomalías de las células de la sangre.

Fenofibrate podría posiblemente dañar el riñón. Los análisis de sangre se realizan periódicamente para observar su función renal. Si los resultados no son normales se reducirá su dosis de fenofibrato o placebo (cual quiera que esté tomando). Si los valores no mejoran, el medicamento se detiene por completo. Después que la dosis se reduce o se detiene el médico del estudio continuará monitoreando sus funciones renales. (También, ver discutió 'Interacciones medicamentosas' a continuación.)

Interacciones con otros medicamentos

¿Cuáles son algunas de las formas en que los fármacos del estudio pueden interactuar? La Administración de Alimentos y Medicamentos (FDA) ha aprobado todos los medicamentos que se utilizarán en ACCORD. La mayoría han sido de formulario utilizado desde hace muchos años. Por lo tanto, sabemos mucho sobre el modo de acción y cómo interactúan con otros medicamentos - especialmente otros tratamientos que se utilizarán en este estudio.

Los investigadores saben que el uso de una sulfonylurea (un tipo de medicamento que reduce el azúcar en la sangre) con ciertos otros medicamentos debe ser evitado. Su médico del estudio se asegurará de que usted no toma este tipo de medicamentos al mismo tiempo.

Los investigadores saben que el uso de statins y fibratos juntos puede aumentar el cambio de ciertos efectos secundarios tales como problemas en el hígado y el dolor muscular y la inflamación. Estos efectos secundarios son raros, pero son más propensos a las dosis de statins más altas. Si la dosis de simvastatina se aumenta a 40 mg por día, su riesgo de sufrir efectos secundarios puede ser aumentado. El estudio de ACCORD tendrán cuidado cuando se le da una combinación de simvastatina y fenofibrato. Muchos médicos hacen uso de esta combinación y han recibido permiso de la FDA para probar la combinación. Además, la clínica ACCORD hará chequeos de sangre para asegurarse que los medicamentos del estudio no están dañando su hígado o los músculos. Estas pruebas se realizaran a 1, 4, 6, 12 meses después de comenzar los medicamentos, y cada año después de ello. Si su médico piensa que el estudio de estatinas y fibratos medicamentos están causando problemas para usted, entonces él / ella puede quitarle uno o ambos medicamentos.

Si usted es elegible para estar en la parte lipídica de ACCORD y si usted está en Comodín (también llamado warfarina), su médico personal será informado por teléfono y por escrito que usted pudiera estar tomando fenofibrato. Debido a que el uso de fenofibrato por lo general significa que su dosis de Comodín debe reducirse para evitar el riesgo excesivo de sangrado, le pondrá a prueba para ver si su sangre se coagula rápidamente. Este análisis de sangre puede hacerse por la clínica ACCORD o por su médico privado. No se le asignara como lanzamiento de moneda hasta que la clínica ACCORD hable con su médico privado acerca de la supervisión de la dosis adecuada de Comodín para usted. Si es colocado en Comodín durante el estudio, tendrá que asegurarse que su médico privado es notificado de la posibilidad que usted puede estar tomando fenofibrato.

BENEFICIOS POTENCIALES:

¿Cuáles son los posibles beneficios? El tratamiento ACCORD puede o no puede ser de beneficio personal para usted. La colección de información del estudio será muy importante para el tratamiento de la diabetes en el futuro. No habrá cargo para cualquiera de las pruebas y procedimientos necesarios para este estudio. Visitas a la clínica, exámenes físicos, pruebas de laboratorio, electrocardiogramas y

otros procedimientos relacionados con los aspectos de investigación de este estudio son pagados por el estudio. Además, los medicamentos para el control del azúcar en sangre, así como para la parte de control de la presión arterial o de la parte de control de lípidos en la sangre de ACCORD (cualquier parte que se encuentre) serán proporcionados a usted de forma gratuita. No se le paga por su participación en este estudio.

TRATAMIENTOS ALTERNATIVOS:

Si usted decide no participar, ¿qué otras opciones tiene? Usted no tiene que participar en este estudio de investigación con el fin de recibir el tratamiento. Un número de tratamientos estarán disponibles para la diabetes, presión arterial alta o colesterol alto. Estos tratamientos incluyen medicamentos, dieta, ejercicio y pérdida de peso. Si usted decide dejar de participar en este estudio, su médico personal debe administrar su atención médica.

INVESTIGACION RELACIONADAS A LESIONES:

¿Qué pasará si se enferma durante el estudio o sufre una complicación relacionada con el tratamiento que está recibiendo como parte del estudio? Como no es probable que usted sufre problemas graves de salud como resultado de su participación en este estudio, el tratamiento médico que es una parte de este estudio conlleva un pequeño riesgo de problemas de salud graves. En el caso de que esta investigación actividad provoca una lesión, el tratamiento estará disponible, incluyendo primeros auxilios, tratamiento de urgencia y los cuidados de seguimiento según sea necesario. Atención a este tipo de lesiones se le cobrará en la forma ordinaria, a usted o/a su compañía de seguros. NHLBI (que patrocina el estudio) no pagará por lesiones.

CONFIDENCIALIDAD:

¿Cómo se protegerá su privacidad? Cualquiera información obtenida acerca de usted durante este estudio será tratada con estricta confidencia hasta la extensión permitida por la ley aplicable. Para garantizar la confidencialidad, se le asignara un número de código. Su nombre y cualquier otra información potencialmente identificándole no se utilizarán en ningún dato o muestras que usted entrega. Sin embargo, su nombre y número de seguro social y números de Medicare serán registrados y almacenados de forma centralizada para ayudar a la llevar un registro del estudio de cualquier enfermedad que usted puede experimentar. Además, con el fin de recibir gratis suministros (Glucos tiras) para medir su glucosa en la sangre durante el juicio, tendrá que proporcionar la información que permita la facturación de Medicare (si está cubierto) y / o cualquier otro seguro que pueda tener (si lo tiene).

Usted no será identificado en ningún informe de la publicación de este estudio.

Sus registros de este estudio pueden ser revisados por los representantes autorizados de la Nacional del Corazón, los Pulmones y la Sangre, la Food and Drug Administration (FDA) y la supervisión del personal de la Oficina de la Red de Minnesota Centro Clínica para el estudio en el Centro Berman para la Investigación de Resultados y por el comité a cargo de proteger a los participantes de investigación en la Universidad de Minnesota.

Al final del estudio, todas las formas con su nombre u otra información de identificación se mantendrán en una habitación cerrada por un período de cinco años. Sólo su médico del estudio o los compañeros de trabajo que ayudan al médico tendrán acceso a estas formas. Después de cinco años, se destruirán.

También al final del estudio, el Centro Coordinador proporcionará el Instituto Nacional del Corazón, los Pulmones y la Sangre (NHLBI) los datos del estudio, sin identificación información personal como su nombre, dirección, número de seguro social o número de Medicare. Orina, sangre y / o materiales tomados de usted durante el estudio se considerará donación de su parte a la investigación médica. Estos materiales también se pueden compartir a la NHLBI al final del estudio, de nuevo sin información de identificación personal. Los materiales e/o datos pueden ser compartidos con otros científicos que cumplan con los requisitos del NHLBI, incluyendo el tratamiento de los datos o materiales como médicamente confidencial, obteniendo aprobación del comité de juntas de revisión de los sujetos humanos, y comprometiéndose a no compartir los datos o materiales con otros partidos. Las compañías farmacéuticas que han contribuido las drogas, y en algunos casos el dinero, para el estudio ACCORD también se proporcionaron datos del estudio y sin ninguna información de identificación personal.

CERTIFICADO FEDERAL DE EE.UU DE CONFIDENCIALIDAD

Es particularmente importante que usted sepa que ACCORD se ha concedido un certificado de confidencialidad por parte del Gobierno Federal de los Estados Unidos para asegurarse la mejor manera de proteger su privacidad. Este certificado significa que los investigadores de ACCORD no pueden ser obligados a decir a nadie no conectado con el estudio acerca de su participación. Esto incluye los tribunales y la policía. Los investigadores sólo podrán divulgar información si usted lo solicita.

Hay algunos límites a la capacidad del investigador para mantener su confidencialidad. Si nos enteramos que mantener su información privada lo pondría en peligro inmediato o poner a otra persona que sabemos en peligro inmediato, entonces vamos a tener que decirle a las agencias apropiadas para proteger a usted o la otra persona.

LA NATURALEZA DE SER VOLUNTARIO EN EL ESTUDIO:

¿Qué pasa si usted quiere salirse antes que el estudio termine? La participación en este estudio es voluntaria. Usted puede optar no participar o puede retirarse del estudio en cualquier momento. Negarse a participar o abandonar el estudio no dará lugar a ninguna sanción o pérdida de beneficios a los que tiene derecho. Su médico del estudio también tiene el derecho de detener su participación en este estudio en cualquier momento. Esto podría ser porque usted ha tenido una reacción inesperada, o ha dejado de seguir las instrucciones, o porque todo el estudio se ha detenido.

NUEVA INFORMACION

¿Qué pasa si aprendemos sobre los nuevos riesgos durante el estudio? Se le dará toda la información nueva obtenida durante el curso del estudio que pueda afectar su salud, el bienestar o la voluntad de permanecer en el estudio ACCORD. Los resultados de sus pruebas de laboratorio y mediciones clínicas serán proporcionados a usted para que comparta con su médico personal.

PREGUNTAS SOBRE EL ESTUDIO:

¿Qué pasa si usted tiene preguntas sobre este estudio? Si tiene preguntas sobre el estudio o en el caso de una lesión relacionada con la investigación, comuníquese con el investigador del estudio, la doctora

Elizabeth R. Seaquist en el University de Minnesota, MMC 101, 420 Delaware St. SE, Minneapolis, MN 55455, teléfono 612- 626-1960.

Si usted tiene alguna otra pregunta o inquietud con respecto al estudio y le gustaría hablar con alguien que no sea el investigador (s), comuníquese con la Línea de Ayuda de Investigación Fairview, al teléfono 612-672-7692 o gratis al 866-508-6961. También puede comunicarse con esta oficina por escrito o en persona en la Universidad de Fairview Medical Center - Riverside Campus, # 815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

ESTUDIOS GENETICOS:

¿Cuál es el objetivo de los estudios genéticos? Uno de los objetivos de ACCORD es examinar su material genético (ADN) y su relación con los efectos de los tratamientos. Si decide participar voluntariamente en los estudios genéticos necesitaran una muestra de sangre (aproximadamente 1 cucharadita) para obtener el ADN de sus células sanguíneas. La información obtenida de la investigación sobre el ADN puede ser utilizado para desarrollar nuevas maneras de detectar o tratar enfermedades graves.

¿Qué pasará con las muestras de ADN? Si usted acepta participar en los estudios genéticos, el ADN puede ser examinado directamente o utilizar para crear una muestra de tejido vivo (o línea celular). La creación de esta línea celular da a los investigadores un suministro ilimitado de ADN que pueden utilizar en el futuro sin tener que tomar más la sangre de usted. La línea celular no es un clon humano.

¿Las muestras de ADN se comparten con otras instituciones? Con su permiso, el Laboratorio Central ACCORD puede compartir muestras de ADN con los investigadores que participan en ACCORD. Si usted da permiso, las muestras también se pueden compartir con otros laboratorios de investigación que estudian la genética de la diabetes tipo 2 y enfermedades del desarrollo de corazón y vasos sanguíneos, de otras enfermedades importantes, condiciones de salud o factores de riesgo. Los científicos de estos laboratorios les darán el ADN sin ninguna información para identificar al usuario.

¿Cómo se utilizarán las muestras de ADN en el futuro? La información obtenida de la investigación en su línea de células o ADN puede ser utilizado para desarrollar nuevas maneras de detectar o tratar enfermedades graves.

¿Cómo será la información genética mantenida privada? Sólo el Laboratorio Central tendrá acceso a las muestras. Ningún otro individuo, incluyendo su cónyuge, padres, hijos, el médico o el empleador tendrá acceso a la muestra almacenada o información obtenida de la muestra almacenada. Al final del estudio, las muestras se pueden proporcionar a otros investigadores, en determinadas condiciones, sin ningún tipo de información de identificación personal (Vella "Privacidad" más arriba).

¿Por cuánto tiempo se mantendrán las muestras de ADN? Su muestra se puede mantener hasta que no haya más valor científico de ella. Si, en cualquier momento durante el estudio, usted decide que usted que su muestra de ADN no sella almacenada por más tiempo, puede notificar a su coordinador del estudio ACCORD y la muestra será destruida.

¿A quién pertenece la muestra? Al marcar "sí" al final de este documento, usted se ofrece voluntariamente para proporcionar muestras genéticas con fines de investigación médica. Su línea de células o ADN no se venderán a nadie ni a instituciones o empresas para obtener ganancias financieras o beneficios comerciales sin su consentimiento. Sin embargo, ni usted ni sus herederos recibirán el dinero

de cualquier descubrimientos o invenciones realizadas con la información y / o especímenes que usted proporciona.

¿Recibirá los resultados del estudio sobre la investigación con sus muestras? No le darán información de los resultados de la investigación realizada sobre la muestra de su sangre genética, aunque pruebas genéticas pueden realizarse después del estudio de muestras en ACCORD. Si hay alguna información nueva acerca de las pruebas genéticas para la diabetes tipo 2 en relación al corazón, enfermedades de venas sanguinas u otras condiciones de salud, le notificaremos por medio de su médico del estudio si esta información puede ser importante para usted o su familia.

¿Hay algún costo para usted para el almacenamiento de las muestras? No hay ningún costo para usted o su compañía de seguros para el almacenamiento y uso de las muestras.

ACUERDO DE LOS PARTICIPANTES PARA LA PARTE GENETICA DE ACCORD

Por favor, consulte en las siguientes opciones:

_____ **Sí**, estoy de acuerdo en participar en la parte genética de ACCORD.

_____ **No**, estoy de acuerdo para participar en la parte genética de ACCORD

Si usted accedió a participar en la parte genética de ACCORD, por favor marque una de las siguientes situaciones con respecto a las enfermedades que vamos a estudiar:

_____ Estoy de acuerdo en permitir que mi muestra genética sea utilizada para estudiar los genes relacionados con factores de enfermedades graves o condición de salud o riesgo.

_____ Estoy de acuerdo en permitir que mi muestra genética sea utilizada sólo para estudios de los genes relacionados con la diabetes, la presión arterial, alteraciones del colesterol de la sangre, enfermedades del corazón, otras enfermedades cardiovasculares, enfermedades renales, o de otros factores de riesgo para enfermedades del corazón o para la diabetes.

Si usted accedió a participar en la parte genética de ACCORD, por favor marque uno de los siguientes investigadores respecto a que tendrán acceso a las muestras genéticas:

_____ Estoy de acuerdo en permitir que mis muestras genéticas sean utilizadas en estudios por los investigadores de ACCORD, así como por otros investigadores que cumplan con las normas y procedimientos del NHLBI.

_____ Estoy de acuerdo en permitir que mis muestras genéticas sean utilizadas **SOLO** en estudios por los investigadores de ACCORD.

ACUERDO DEL PARTICIPANTE PARA EL ESTUDIO ACCORD

He leído la información proporcionada anteriormente. Yo voluntariamente doy consentimiento para participar del estudio ACCORD.

_____ _____

Firma del participante Fecha

_____ _____

Nombre del participante	**Fecha**
_____	_____
Firma de la persona que obtiene el consentimiento	**Fecha**
_____	_____
Nombre de la persona que obtiene el consentimiento	**Fecha**

Appendix V

Original ACCORD Consent Form English

Consent Form

(Consent Version Date: May 27, 2005)

ACTION TO CONTROL CARDIOVASCULAR RISK IN DIABETES (ACCORD)

Principal Investigator: Elizabeth. Seaquist MD, Department of Medicine, University of Minnesota

You are invited to join in a research study called Action to Control Cardiovascular Risk in Diabetes (ACCORD), which is sponsored by the National Heart, Lung and Blood Institute (part of the U.S. federal government). You are being invited to participate in ACCORD because you have Type 2 diabetes along with other factors that increase your chance of having future heart disease and stroke, or you may already have had heart disease or stroke.

The investigator listed above is in charge of the study. Other professional persons may help or act for Dr. Seaquist.

Details about this study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You will be given a copy of this consent form. You are urged to ask the investigator named above, or staff members who may assist her, any questions you have about this study at any time.

Background Information:

What is the purpose of the study and how long will it last? Type 2 diabetes is very common in North America. People with Type 2 diabetes have a higher chance of getting heart disease or stroke than people without diabetes. The purpose of the ACCORD study is to determine the best approaches to lower the risk of heart disease and stroke in people with Type 2 diabetes.

ACCORD will answer three research questions. In diabetes, the level of sugar in the blood is too high. So the first question is to determine the effects of lowering blood sugar to a level below that normally targeted in current clinical practice, compared with a level that is usually targeted. Many diabetic patients have high blood pressure. So the second question is to determine the effects of lowering blood pressure to a level below that normally targeted in current clinical practice, compared with a level usually targeted. Many diabetic patients also have problems with their blood lipids (like cholesterol, fat-like materials in the blood). So the third question is to determine the effects of treating several components of blood lipids compared with treating only one component. Each of these questions is described in more detail below.

Your participation in the study will last until June 2009. However, study results will be reviewed regularly to see if the trial should be stopped earlier than this. Most participants will be in the ACCORD study between 5 1/2 and 8 1/2 years.

The total number of participants will be about 10,000 from approximately 70 clinics throughout the United States and Canada. The study will involve approximately 250 patients at the University of Minnesota clinical site. ACCORD recruited about 1,200 participants during the Vanguard (pilot) portion of the trial in 2001 and these participants are still being treated and followed.

PROCEDURES:

What will happen if you take part in this study? Initial visits will be conducted to determine whether you qualify for the study. These are called "screening" visits. Your medical history, blood pressure, and past blood sugar and cholesterol measurements will be reviewed to determine whether you qualify for the study. You will have a short physical exam, and one tube (about 2 teaspoonfuls) of blood may be collected and tested for creatinine (a measure of kidney function), lipids and liver function. Some urine will also be collected and tested for protein.

If you qualify for the study and volunteer to participate, your study doctor will treat your blood sugar and either your blood pressure or your blood lipids according to the ACCORD study protocol. You and your personal physician are still responsible for other parts of diabetes care, including general preventive measures, foot care, and eye care. If you are not in the blood pressure part of ACCORD, your personal physician will still be responsible for treating your blood pressure. If you are not in the blood lipids part of ACCORD, your personal physician will still be responsible for treating your blood lipids (such as blood cholesterol). In addition, you will still need to see your personal physician(s) for all other medical care.

Blood sugar treatment groups. If you qualify and consent, you will be randomly assigned (like the flip of a coin) to one of the two blood sugar goals. The "intensive" goal is a blood sugar level lower than the current recommended value. The "standard" goal is a blood sugar level similar to the current recommended value. Your current treatment for diabetes (if any) will be changed to study treatment based on the goal to which you are assigned. Your study treatment will use available and approved diabetes treatments (oral medications and/or insulin as may be required).

If you are randomized to the intensive blood sugar goal, it is very likely that you may need one or more of the following: a) at least 2 oral medications; b) 3 or more insulin injections per day; c) frequent self-adjustment of insulin; and d) frequent home glucose monitoring. This means you will probably have to take several pills, give yourself insulin injections with a small needle, and do finger sticks to test your blood sugar up to eight times a day.

The degree of control of blood sugar is best measured by a test called hemoglobin A1c. This test gives an average of your sugar values during the past 2 to 3 months. If you are in the intensive blood sugar treatment group, the goal will be to keep your hemoglobin A1c at less than 6.0% (which is about an average blood sugar of 115 mg/dl (6.4 mmol/L)). This level is much lower than usually achieved in clinical practice. If you are in the standard blood sugar treatment group, the goal will be to keep your

hemoglobin A1c value between 7.0% and 7.9% with the average around 7.5% (average blood sugar of 160 mg/dl (8.9 mmol/L)). This level is also lower than that usually achieved in clinical practice. Lowering hemoglobin A1c to this level from higher levels has been shown to reduce complications of diabetes like eye and kidney diseases. Your diabetes medications may be adjusted upwards or downwards, as your study doctors try to reach these blood goals safely.

Compared to the intensive target of a hemoglobin A1c of less than 6.0%, the standard hemoglobin A1c target of 7.5% has a somewhat higher risk for some diabetes complications. These include eye disease (retinopathy), kidney disease (nephropathy), and abnormal nerve function (neuropathy). On the other hand, a hemoglobin A1c of less than 6.0% will increase somewhat the risk for developing serious low blood sugar reactions (hypoglycemia) and weight gain. Whether the lower hemoglobin A1c target gives more or less protection against cardiovascular disease (such as heart attack or stroke) is not known. This is what ACCORD is trying to find out.

In the standard group, ACCORD will take action and recommend treatment to lower your blood sugar if your hemoglobin A1c value becomes greater than 7.9%. If your hemoglobin A1c drops below 7.0% and you are taking insulin or a secretagogue (like glimepiride or repaglinide), we may reduce your diabetes treatment to try to bring your value above 7.0%. In the intensive group, if your hemoglobin A1c value becomes even slightly greater than 6.0%, we will increase your treatment.

Depending on your initial blood pressure and blood cholesterol results, you will also be asked to participate in either the blood pressure or cholesterol parts of the study. You must participate in one or the other (based on your qualifications) to participate fully in ACCORD.

Blood pressure treatment groups. Blood pressure lowering can prevent heart disease, stroke, and kidney disease. There is some evidence that lowering blood pressure further than current practice might help prevent heart disease and stroke in people with diabetes. This possibility needs careful testing in a study such as this one.

If you qualify for the blood pressure portion of the study, you will be randomly assigned (like the flip of a coin) to one of two blood pressure goals. The "intensive" goal is a blood pressure level lower than that already proven to reduce heart disease and stroke. The "standard" goal is a blood pressure level similar to that already proven to reduce disease. Your study doctor will choose the medications he/she feels will be best for treating your blood pressure. Therefore, your current blood pressure medication (if any) could be changed or continued. If you do not reach your blood pressure goal, your study doctor will change your treatment until you do.

Blood lipid treatment groups. Lowering blood cholesterol can prevent heart disease and stroke. There is also some evidence that changing other blood lipids by lowering triglycerides (a type of fat in the blood) and raising HDL-cholesterol (the good cholesterol) may prevent heart disease in people with diabetes. This possibility needs careful testing in a study such as this one.

If you are eligible to participate in the blood lipid study, your current cholesterol medication treatment (if any) will be stopped and changed to the study medication. You will be treated with cholesterol-lowering medication commonly known as a "statin". **The statin used in ACCORD is called simvastatin.**

The dose of simvastatin you are started on will depend on your medical history. If you have had a heart attack, stroke, heart surgery, surgery on your arteries (blood vessels) or angina (chest pain) with changes in an electrocardiogram (EKG or ECG), you will be started on 40 mg of simvastatin. If you have not had any of those, you will receive 20 mg of simvastatin.

Regardless of your assigned dose of simvastatin, ~~Everybody in the lipid portion of ACCORD will receive 20 mg a day of the statin called simvastatin.~~ **you will** be randomly assigned (like the flip of a coin) to a medication known as a fibrate to lower your triglycerides and raise your HDL-cholesterol, or to a placebo (a pill that does not contain any medicine). The fibrate used in ACCORD is called fenofibrate. Neither you nor your doctor will know which study treatment (placebo or fibrate) you are receiving. If it becomes necessary to know for medical reasons, the information will be made available.

If **you begin ACCORD at the 20 mg dose of simvastatin and** your cholesterol levels remain higher than the currently recommended level, **or if you have a heart attack, stroke, heart surgery, surgery on your arteries (blood vessels) or angina (chest pain) with changes in an electrocardiogram (EKG or ECG) during the study,** your dose of simvastatin will be increased to 40 mg per day. If your cholesterol level remains too high despite the treatment with **the increased dose of** simvastatin, you will be taken off the study medications and sent to your personal doctor to get appropriate treatment to reduce your cholesterol level.

Fenofibrate could possibly harm the kidney. Blood tests will be done regularly to look at your kidney functioning. If your results are not normal your dose of fenofibrate or placebo (whichever you are on) will be reduced or stopped. After your dose is reduced or stopped, your study doctor will continue to monitor your kidney function.

Genetic component. Genetic research will be done as part of this study. You may, if you wish, volunteer for the genetic portion of the study. If you volunteer to participate in the genetic portion of ACCORD, your blood will be stored for genetic (DNA) analysis. The genetic portion of ACCORD is described in more detail below. You do not need to agree to participate in the genetic studies to participate in the main ACCORD study.

Visit schedule and measurements. If you qualify for ACCORD and are assigned to the standard blood glucose group and either the lipid trial or the standard blood pressure group, you will be asked to visit the clinic at one month, four months, and every four months thereafter for the duration of the trial. If you are assigned to any of the other groups, you will be asked to come every month for the first four months of the study and then at least every two months thereafter until the end of the study.

At each clinic visit, your health will be reviewed, and any symptoms you may have will be discussed with the study doctor or nurse or other study staff. Your weight, blood pressure, and heart rate will be measured, and your study medications will be reviewed to make sure you are taking them correctly. You will receive nutrition and physical activity recommendations and will be taught how to follow them. In addition, a member of your ACCORD study care team may contact you by phone between your clinic visits to determine how you are feeling and whether or not further action is required to control your blood sugar or blood pressure levels.

You will have blood specimens (up to five tablespoons) drawn every four months for the first year and once a year thereafter. These tests will measure blood sugar, potassium, kidney function, and liver function. You will also be asked to allow blood and urine specimens to be taken and stored for future non-genetic studies. Also, additional blood samples may be taken occasionally to monitor your treatments for safety, which may require you to come in for additional visits.

If you are assigned to the "intensive" blood sugar goal you will have more frequent blood sugar testing by the clinic. This testing will range from once per month during the first 4 months of treatment to every two months thereafter. If you are in the cholesterol study, your blood cholesterol will be measured every four months during the first year and every year thereafter until the end of the study. You will also have blood drawn every four months throughout the study to check your kidney function. If you are not in the cholesterol study, you will have your cholesterol measured every year. As part of diabetes management, you will be expected to check your own blood sugar, as discussed later. Some urine will be collected at the baseline visit and every two years thereafter so that it can be examined for urine protein and creatinine (a measure of kidney function). You will also have an electrocardiogram (a recording of the electrical activity of the heart, also called an ECG or an EKG) at baseline and every two years thereafter. A limited eye exam will be done every other year.

You also have about a 1-in-5 chance of being chosen to complete questionnaires about your quality and activities of life, and your diet and physical activity levels. These questionnaires will be given at the beginning of the study, at 1 and 3 years, and at the 4 year visit. The questionnaires will take about one hour of your time. In addition, you may be chosen to participate in a group where health care costs will be monitored (and you would be asked to give permission to obtain records from any hospitalizations).

Certain medical procedures are recommended for people with diabetes that are not part of the research study. These include annual eye exams by an ophthalmologist, annual foot exams, annual flu and pneumococcal vaccinations, and electrocardiograms (ECGs or EKGs). The study eye examination does not replace the recommended annual eye exams by an experienced eye care professional, such as an ophthalmologist (a doctor who specializes in the diagnosis and treatment of eye diseases).

During the course of the trial, our central Coordinating Center at Wake Forest University School of Medicine, or its representatives may contact you, about your participation in

the trial. For example, you may be asked if you are having any trouble taking any of your medications. You may also be asked how you are feeling and whether you have been in the hospital for any reason, why and where you were hospitalized.

POTENTIAL RISKS OF PARTICIPATING IN THE ACCORD STUDY:

What are the possible risks and discomforts? Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are considered to be abstinence (not having sex), oral contraceptives (the pill), intrauterine device (IUD), DepoProvera, Norplant, tubal ligation (tubes tied), or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable method, involves the careful use of condoms and/or a spermicidal foam or gel along with a diaphragm, pervical cap, or sponge. We encourage you to discuss this issue further with your doctor if you have any questions.

If you are a pregnant woman, you cannot participate in this study. Because some methods of birth control are not 100% reliable, a negative pregnancy test is required at least 10 days after your last normal menstrual period if you are a sexually active woman of childbearing potential.

This study requires that blood be drawn from a vein in your arm several times during the study. Drawing blood may result in pain at the point of puncture, a feeling of faintness, irritation of the vein, and bruising or bleeding at the site of the needle stick. There is also a very slight possibility of an infection at the needle puncture site. The study visits, procedures, and lab work might be more often than your medical conditions usually require, but they are very important for the study.

This study requires daily finger-stick measurements of your blood sugar level. You probably have experience testing your blood sugar by finger-stick before coming into the study. You need to test your blood sugar daily because it is very important for the study that you keep your blood sugar values at the assigned goal. If you are assigned to the intensive blood sugar goal, there is a good chance that at some point you will be asked to do up to eight finger sticks a day to properly correct your blood sugar. Your blood sugar checks will be reviewed by clinic personnel and will be used to figure out your treatment plan. Clinic personnel, or others working for ACCORD, may contact you to discuss your blood sugar results.

Treating blood sugar in persons with diabetes can sometimes cause blood sugar to be too low. This condition, called "hypoglycemia", can result from changing diet, exercise, or medications. Symptoms are usually mild but sometimes can be more serious.

Mild symptoms of hypoglycemia include hunger, anxiety, dizziness, or light-headedness. Sometimes there is sweating, fatigue or mild confusion, tremors (shaking) or palpitations (feeling your heart beating in your chest). Hypoglycemia may cause loss of

consciousness. If this occurs while operating machinery such as driving a car, it can result in injury or even be life threatening.

In rare cases, hypoglycemia can be very severe and require emergency treatment or hospitalization. Severe hypoglycemia may cause brain damage, coma, or death. Severe hypoglycemia can occur in any patient taking medication to lower blood sugar. It is more likely to occur in those treated with insulin to achieve lower glucose targets, as in the intensive treatment group of this study.

A sugar-containing drink such as fruit juice usually quickly relieves the milder symptoms. You may be given sugar pills to raise you blood sugar if you have symptoms. Medications are sometimes needed to treat severe hypoglycemia. These may include intravenous (i.v.) fluids or injections of glucagons, a medication that rapidly increases blood sugar.

Regardless of which blood sugar treatment group you are assigned to, safety will always be of first importance when changes in the management of your blood sugar are made. Based on data from previous studies it is estimated that, in the intensive group, about six out of 100 participants will have a serious complication (such as hospitalization or emergency room visit for hypoglycemia) every year. In the standard group about 2 participants may have such a complication every year. In either group, ACCORD doctors and nurses will take action to lessen the risk of hypoglycemia should it occur too often or in a severe form. On the other hand participants in the standard group may have a somewhat higher risk of complications related to diabetes (like eye, kidney disease or abnormal nerve function). It is estimated that, in the intensive group, about one out of 100 participants will have such a complication every year. In the standard group about 1.5 participants may present such a complication every year.

If you are assigned to the intensive blood pressure group, you may experience blood pressure that is too low. Symptoms of low blood pressure may be mild, such as feeling a little lightheaded, or less often may be more severe, such as dizziness, fatigue, or fainting. Sitting or lying down often relieves these symptoms. You should notify your clinic doctor or nurse if you have these symptoms. Clinic staff will follow you closely to lower your chances of having too-low blood pressure.

What are the side effects of the medicines used in the study? All drugs have a potential risk of an allergic reaction, which if not treated quickly, could become life threatening.

You may have side effects from the specific medications chosen as treatments. Medications that may be used at this time in ACCORD are listed below. Additional medications may be chosen in the future. The ACCORD staff will tell you about any new medicines that they may give you.

Possible side effects for the classes of medications include the following. Your doctors have ways to manage these effects.

Blood sugar treatments

Sulfonylureas [glimepiride]: The most common side effects associated with this family of medicines include hypoglycemia (low blood sugar), weight gain, and allergies. Very rarely, blood cell abnormalities may occur. Your doctor has ways of managing the blood cell abnormalities.

Biguanides [metformin]: Common side effects associated with this drug class include nausea, vomiting, diarrhea, bloating, loss of appetite, or metallic taste in the mouth. These usually get better after the first few weeks of treatment. If these treatments are stopped, the side effects will go away over a day or two. Very rarely, people can have a severe reaction known as lactic acidosis (a condition that occurs when your body fluids and tissues have too much acid in them). Lactic acidosis almost always occurs in people with advanced kidney disease, liver disease or heart failure, and in people who drink alcohol heavily. Every effort will be made to avoid using this drug in people with those conditions.

Thiazolidinediones (TZDs) [rosiglitazone, **pioglitazone**]: The most common side effects related to this group of medicines include fluid retention (a condition that occurs when your body holds in too much water) and weight gain. Although the 4 mg/day dose of rosiglitazone (the TZD to be use in ACCORD) is the only dose of rosiglitazone that has been approved by the U.S. FDA for use with insulin, higher doses of rosiglitazone, which you may be placed on, have been combined with insulin in medical practice. The use of drugs like rosiglitazone together with insulin may cause fluid retention, which could lead to or worsen heart failure. Heart failure is a decreased ability to pump enough blood throughout the body. Symptoms of heart failure include shortness of breath, cough, fatigue, tiredness, ankle swelling, or weight gain. If your doctor prescribes insulin together with rosiglitazone, you will be monitored closely for these symptoms, so that the medications can be adjusted or, if necessary, stopped.

Although there has been no report of liver difficulties with rosiglitazone, a related medication was removed from the market due to rare, severe liver reactions. Thus, if you require this medication, you will need to have blood tests looking for liver problems every two months for the first year after you begin the medication and once a year thereafter.

Insulin [various short-, intermediate-, or long-acting forms, including Aspart and glargine]: Potential side effects related to insulin use include: low blood sugar, low potassium in the blood, allergies or skin changes.

Meglitinides [Repaglinide]: Common side effects include headache, upper respiratory infections, nausea, vomiting, constipation, and diarrhea. The most serious side effect is hypoglycemia.

Alpha-glucosidase inhibitors [acarbose]: Side effects include flatulence (gas), and abdominal discomfort. These are generally mild to moderate in severity and usually diminish in frequency and intensity with time. Very rarely, this medication may cause skin reactions, hepatitis, and/or jaundice (yellowing of the skin or whites of the eyes, indicating possible liver problems).

Blood pressure treatments

Angiotensin Converting Enzyme Inhibitors (ACE-I) [benazepril, lisinopril, ramipril]: Potential side effects associated with this type of medicine include: dizziness, headache, fatigue, nausea, diarrhea, cough, rash, high potassium in the blood, low blood pressure upon standing, harm to kidney function and rarely angioedema (swelling of the face, lips and tongue that can result in difficulty breathing or in rare cases, death).

Diuretics [chlorthalidone, hydrochlorothiazide]: Potential side effects associated with this class of medication also known as "water pills" include: muscle cramps, nausea, vomiting, diarrhea, dizziness, rash, weakness, low blood pressure, low potassium, high blood sugar, partial or total lack of ability to perform sexual function, and gout (a painful joint condition that occurs when too much acid and salt build up in the blood stream and joints).

Beta Blockers [metoprolol]: The most common side effects associated with this group of medicines include: dizziness, fatigue, stomach upset, depression, cold hands and feet, low blood pressure, changes in heart rhythm and heart rate, and decrease in sexual function. Beta-blockers may also hide some of the symptoms but not the hazards of low blood sugar. . **If you begin taking these medications, you should not stop taking them without talking to your study doctor first.**

Calcium Channel Blockers [isradipine, diltiazem, amlodipine, nifedipine]: The most frequent side effects associated with these medications are: ankle or foot swelling, dizziness, flushing, palpitations (awareness of your heartbeat), headache, fatigue, nausea and abdominal discomfort. **Occasionally, severe hypotension (abnormally low blood pressure) may occur when starting these medications of adjusting their dose. Rarely, increased angina (chest pain) and myocardial infarctions (heart attacks) may occur in people with severe coronary disease. When combined with a beta blocker, the medication nifedipine may cause congestive heart failure (a decreased ability to pump enough blood through the body), which can be serious but is very rare.**

Alpha Blockers [terazosin]: Potential side effects associated with this category include: fainting, dizziness, fatigue, swelling, low blood pressure, partial or total lack of ability to perform sexual function, changes in heart rhythm and certain blood cell abnormalities.

A-II Receptor Blockers [candesartan, valsartan]: The most common side effects are dizziness, headache, fatigue, diarrhea, muscular-skeletal pain. More serious side effects are angioedema (swelling of the face, lips and tongue that can result in difficulty breathing or in rare cases, death) and severe hypotension. This family of drugs may also effect your kidney function. Your doctor may do blood tests to see if your kidneys are performing properly.

Loop Diuretic [furosemide]: rare side effects include thrombocytopenia (low platelet count), rash, pancreatitis (inflammation of the pancreas), jaundice (yellowing of the skin

or whites of the eyes) indicating possible liver problems. Serious side effects include abnormalities in blood cells.

Sympatholytics [reserpine]: The most common side effects include dizziness, dry mouth, nausea, vomiting, nasal congestion, peripheral edema (too much fluid in the body's tissues), stomach cramps, headache, impotence, depression, nervousness, shortness of breath, nightmares, difficulty with urination, shaky hands, and anorexia (poor appetite). More serious side effects include dysrhythmias (heart rhythm abnormalities), black tarry stools, hematemesis (vomiting blood), bradycardia (slow heart rate), chest pain, and thrombocytopenia (low platelet count).

Vasodilators [hydralazine]: Side effects include headache, tachycardia (fast heart rate), angina (chest pain), and palpitations. Rare but more serious side effects include abnormalities in blood cells and lupus-like syndrome.

Potassium Sparing Diuretics [triamterene]: The most common side effects include diarrhea, nausea, vomiting, gastrointestinal distress, dizziness, dry mouth, pruritis (itching), rash, sensitivity to light, weakness, hypotension, muscle cramps, blood chemical imbalances (such as too much potassium), impaired kidney function, elevated uric acid, blood cell abnormalities and reduced folic acid stores. More serious possible side effects include increased acid in the blood and shock due to an allergic reaction to the medication.

Alpha-beta blockers [carvedilol]: The most common side effects are dizziness and fatigue. The more serious side effects include AV block (a heart rhythm disturbance), bradycardia (slow heart rate), thrombocytopenia (low platelet count), and bronchospasm (tightening of breathing airways). Alpha-beta-blockers may also hide some of the symptoms but not the hazards of low blood sugar.

Lipid treatments

HMG-CoA Reductase Inhibitors (statins) [simvastatin]: Common side effects associated with this class of cholesterol-lowering medications include: headache, dizziness, stomach upset. Rare, but more serious side-effects are muscle aches, rash and elevated liver enzymes (indicating possible liver problems) in the blood. (Also, see 'Drug Interactions' discussed below.)

Fibrates [fenofibrate]: Potential side effects associated with these medications include: abdominal pain, stones in the gall bladder, jaundice (yellowing of the skin and/or whites of the eyes indicating possible liver problems), headache, change in taste, elevated liver and kidney function tests, and certain abnormalities in blood cells. Your study doctor has ways to manage these blood cell abnormalities.

Fenofibrate could possibly harm the kidney. Blood tests will be done regularly to look at your kidney function. If your results are not normal your dose of fenofibrate or placebo (which ever you are on) will be reduced. If the values do not improve, the medication will be stopped entirely. After your dose is reduced

or stopped your study doctor will continue to monitor your kidney functions. (Also, see 'Drug Interactions' discussed below.)

Drug Interactions

What are some of the ways the study drugs can interact? The Food and Drug Administration (FDA) has approved all drugs that will be used in ACCORD. Most have been used for many years. Therefore, we know much about the way these drugs work and how they interact with other drugs – especially other treatments that will be used in this study.

Researchers know that using a sulfonylurea (a type of drug that lowers blood sugar) with certain other drugs should be avoided. Your study doctor will make sure that you do not take these kinds of medicines together.

Researchers also know that using statins and fibrates together may increase the chance for certain side effects such as liver problems and muscle pain and inflammation. These side effects are rare, but are more likely at higher statin doses. If your dose of simvastatin is increased to 40 mg per day, your chance of side effects may be increased. The ACCORD trial will use caution whenever you are given a combination of simvastatin and fenofibrate. Many doctors do use this combination and we have received permission from the FDA to test the combination. Also, the ACCORD clinic will be checking your blood to make sure that the study medications are not harming your liver or muscles. These tests will be done at 1, 4, 8, and 12 months after you begin the medications, and every year after that. If your study doctor thinks that the statin and fibrate medicines are causing problems for you, then he/she may take you off one or both these medicines.

If you are eligible to be in the lipid portion of ACCORD and if you are on Coumadin (also called warfarin), your personal doctor will be informed both by phone and in writing that you may be on fenofibrate. Because the use of fenofibrate generally means that your dose of Coumadin should be reduced to avoid excessive risk of bleeding, you will be tested to see how fast your blood clots. This blood test can be done by either the ACCORD clinic or by your private doctor. You will not be randomized until the ACCORD clinic staff speaks with your private doctor about monitoring the appropriate dose of Coumadin for you. If you are placed on Coumadin during the study, you will need to make sure that your private doctor is reminded that you may be on fenofibrate.

POTENTIAL BENEFITS:

What are the possible benefits? The ACCORD treatment may or may not be of personal benefit to you. The information gathered from the study will be very important for the treatment of diabetes in the future. There will be no charge to you for any of the required tests and procedures performed during your participation in this study. Clinic visits, physical exams, laboratory tests, electrocardiograms and any other procedures associated with the research aspects of this study are paid for by the study. In addition, your medications for the blood sugar control as well as for the blood pressure control

portion or blood lipid control portion of ACCORD (whichever part you are in) will be provided to you free of charge. You will not be paid for your participation in this study.

ALTERNATIVE TREATMENTS:

If you chose not to participate, what other options do you have? You do not have to participate in this research study in order to receive treatment. A number of treatments are available for diabetes, high blood pressure, or high cholesterol. These treatments include drugs, diet, exercise, and weight loss. If you decide to stop participating in this study, your personal doctor should manage your medical care.

RESEARCH RELATED INJURY:

What will happen if you become ill during the study or suffer a complication related to the treatment that you are receiving as part of the study? While it is not likely that you will suffer major health problems as a result of your participation in this study, the medical treatment that is a part of this study carries a small risk of serious health problems. In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The NIHLBI (which sponsors the study) will not pay for injuries.

CONFIDENTIALITY:

How will your privacy be protected? Any information obtained about you during this study will be treated as strictly confidential to the full extent permitted by applicable law. To ensure confidentiality, a code number will be assigned to you. Your name and any other potentially identifying information will not be used on any data or samples you provide. However, your name and Social Security and Medicare numbers will be recorded and stored centrally to help the study keep track of any illnesses you may experience. Also, in order to receive free supplies (glucose strips) to measure your own blood glucose during the trial, you will need to provide the information that will permit billing for Medicare (if you are covered) and/or other insurance you may have (if you have it.)

You will not be identified in any report or publication about this study.

Your records for this study may be reviewed by authorized representatives from the National Heart, Lung, and Blood Institute, the Food and Drug Administration (FDA) and monitoring personnel from the Minnesota Clinical Center Network Office for the study at the Berman Center for Outcomes Research and by the committee in charge of protecting research participants at the University of Minnesota.

At the end of the study, all forms with your name or other identifying information will be kept in a locked room for a period of five years. Only your study doctor or co-workers assisting the doctor will have access to these forms. After five years, the forms will be destroyed.

Also at the end of the study, the Coordinating Center will provide the National Heart, Lung, and Blood Institute (NHLBI) data from the study, without personal identifying information such as your name, address, Social Security number, or Medicare number. Blood, urine, and/or tissue samples or other materials taken from you during the study will be considered donated by you to medical research. These materials may also be provided to the NHLBI at the end of the study, again without personal identifying information. The data and/or materials may be shared with other scientists who meet NHLBI requirements including treating the data or materials as medically confidential, obtaining approval from their Human Subjects review boards, and agreeing not to share the data or materials with other parties. Drug companies that have contributed drugs, and in some cases money, to the ACCORD study also will be provided study data without any personal identifying information.

U.S. FEDERAL CERTIFICATE OF CONFIDENTIALITY

It is particularly important to you to know that ACCORD has been granted a Certificate of Confidentiality from the United States Federal Government to make sure we can best protect your privacy. This certificate means that the ACCORD researchers cannot be forced to tell anyone not connected with the study about your participation. This includes courts and police. The researchers will only release information if you request it.

There are some limits to the researcher's ability to maintain your confidentiality. If we learn that keeping information private would immediately put you in danger, or put someone else we know about in danger, then we will have to tell the appropriate agencies to protect you or the other person.

VOLUNTARY NATURE OF THE STUDY:

What if you want to stop before your part in the study is complete? Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your study doctor also has the right to stop your participation in this study at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

NEW INFORMATION

What if we learn about new risks during the study? You will be given any new information gained during the course of the study that might affect your health, welfare, or willingness to stay in the ACCORD study. Results of your laboratory tests and clinical measurements will be provided to you to share with your personal physician.

QUESTIONS ABOUT THE STUDY:

What if you have questions about this study? For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Elizabeth R. Seaquist at the University of Minnesota, MMC 101, 420 Delaware St. SE, Minneapolis, MN 55455, telephone 612 626 1960.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-8961. You may also contact this office in writing or in person at Fairview University Medical Center – Riverside Campus, #815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

GENETIC STUDIES:

What is the goal of the genetic studies? One goal of ACCORD is to examine your genetic material (DNA) and its relationship to the effects of the treatments. If you volunteer to participate in the genetic studies you will be asked for a sample of blood (about 1 teaspoon) to obtain DNA from your blood cells. **Information gained from research on your DNA may be used to develop new ways to detect or treat major diseases.**

What will happen to the DNA samples? If you agree to participate in the genetic studies, the DNA may be examined directly or used to create a living tissue sample (or cell line). Creation of this cell line gives researchers an unlimited supply of DNA that they can use in the future without having to draw more blood from you. The cell line is not a human clone.

Will the DNA samples be shared with other institutions? With your permission, the ACCORD Central Laboratory may share DNA samples with researchers participating in ACCORD. If you give permission, samples may also be shared with other research laboratories studying the genetics of type 2 diabetes and the development of heart and blood vessel diseases, other major diseases, health conditions, or risk factors. The scientists from these laboratories would be given the DNA without any information to identify you.

How will the DNA samples be used in the future? Information gained from research on your cell line or DNA may be used to develop new ways to detect or treat major diseases.

How will genetic information be kept private? Only the **Central Laboratory** ~~Study data manager~~ will have access to the samples. No other individual, including your spouse, parents, children, physician or employer will have access to the stored sample or information gained from your stored sample. At the end of the study, your samples may be provided to other investigators under certain conditions, without any personal identifying information (See "Privacy" above).

How long will the DNA samples be kept? Your sample may be kept until it is no longer of scientific value. If, at any time during the study, you decide that you do not wish to have your DNA sample stored any longer, **you may notify your ACCORD study coordinator and** the sample will be destroyed.

Who owns the samples? By checking "yes" at the end of this document, you volunteer to provide genetic samples for medical research purposes. Your cell line or DNA will not be sold to anyone or to institutions or companies for financial gain or commercial profit without your consent. However, neither you nor your heirs will receive money from any discoveries or inventions made using the information and/or specimens you provide.

Will you receive study results of research involving your samples? You will not be informed of the results of the research performed on your genetic blood sample, although genetic tests may be developed after a study of samples in the ACCORD study. If there is any new information about genetic testing for type 2 diabetes and its relationship to heart and blood vessel diseases or other health conditions, you will be informed by your study doctor if this information may be important to you or your family.

Is there any cost to you for storage of the samples? There is no cost to you or your insurance company for the storage and use of the samples.

PARTICIPANT'S AGREEMENT FOR THE GENETIC PORTION OF ACCORD

Please check one of the following choices:

__ **Yes**, I agree to participate in the genetic portion of ACCORD ~~**AND** to allow a living tissue sample (cell line) to be developed for future genetic studies~~

~~____ **Yes, I agree to** participate in the genetic portion of ACCORD **but do not agree to allow a** living tissue sample (cell line) to be developed for future genetic studies~~

____ **No**, I do NOT agree to participate in the genetic portion of ACCORD

If you agreed to participate in the genetic portion of ACCORD, please check one of the following regarding diseases to be studied:

____ I agree to allow my genetic sample to be studied for genes related to any major disease or health condition or risk factors.

____ I agree to allow my genetic sample to be studied **ONLY** for genes related to diabetes, blood pressure, blood cholesterol abnormalities, heart disease, other cardiovascular diseases, kidney diseases, or other risk factors for heart disease or for diabetes.

If you agreed to participate in the genetic portion of ACCORD, please check one of the following regarding investigators who will have access to the genetic samples:

____ I agree to allow my genetic samples to be used for research by ACCORD investigators as well as by other researchers who meet NHLBI standards and procedures.

____ I agree to allow my genetic samples to be used **ONLY** for research by ACCORD investigators.

PARTICIPANT'S AGREEMENT FOR ACCORD STUDY

I have read the information provided above. I voluntarily consent to participate in the ACCORD study.

Participant's signature	Date
Printed name of participant	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Date

Appendix W

ACCORD Consent Transcript Revised Spanish

Consentimiento de ACCORD (55:07)

Bienvenidos y gracias por venir a platicar del estudio de ACCORD (ACCORD es tomando acción para controlar el riesgo de enfermedades cardiovasculares en la diabetes) con nosotras. Ya sé que hablamos del el estudio en el teléfono. Le explique como una resume de ello y le envié un formulario de consentimiento. Entonces hoy quiero revisar el formulario en detalle con usted para que se dé cuenta si esto es algo para que usted participe o no. ¿Tuvo tiempo para revisar el formulario de consentimiento que le mande?

Ok, bueno. Voy a resumir- el propósito de este estudio es que estamos tratando con el tratamiento de personas con diabetes tipo 2 para reducir el riesgo de ataque cardiaco y apoplejía. Y conocemos que el ataque cardiaco y apoplejía es de dos a cuatro veces más grande entre personas con diabetes en comparación a la población general. (1:05) Entonces es una pregunta de suma importancia, porque si podemos encontrar una manera para reducir ese riesgo, tendremos buenas implicaciones para el tratamiento de diabetes en el futuro. Le hemos invitado en participar en este estudio y determinar si es elegible para el estudio. Este estudio es respaldado por National Heart, Lung and Blood Institute (el instituto nacional del corazón, pulmón y sangre), que parte del gobierno de los Estados Unidos and eso significa que el dinero para este estudio viene del gobierno. Entonces los impuestos que pagamos financian este estudio. El doctor principal quien está involucrada en este estudio y empezó este estudio es la Doctora Seaquist. Ella es la especialista de diabetes aquí en la universidad. Empezaremos repasando el consentimiento, por favor interrumpen en cualquier momento que usted tenga preguntas o algo suene raro porque es mi deseo contestarlas al momento cuando ocurran. (2:06) STOP here – ask for comments

Conocemos que diabetes tipo 2 es muy común en Norte América y personas con diabetes tipo 2 corren un riesgo más alto que tengan enfermedades del corazón y apoplejía en vez de aquellos que no tienen diabetes. Entonces repetimos, el propósito es para encontrar las mejores maneras para reducir ese riesgo entre personas con diabetes tipo 2. El estudio de ACCORD responderá tres preguntas. Se entiende que el nivel de la azúcar en la sangre en una persona con diabetes es muy alto. Entonces queremos saber si al reducir la azúcar en la sangre como el doctor lo recomienda y compararlo cuando es más bajo de lo recomendado podrá

reducir el riesgo de ataque cardiaco y apoplejía. También se sabe que personas con diabetes tienen alta presión. Entonces la segunda pregunta es si cuando la azúcar en la sangre se baja más de lo que suele ser normal y eso posiblemente podrá prevenir enfermedad del corazón y derrame cerebral. También se sabe que muchas personas con diabetes tienen problemas con lípidos o el colesterol en la sangre que es la grasa en la sangre. Entonces la tercera pregunta quiere saber si medicamente tratamos con dos componentes distintos de los lípidos en la sangre en comparación a tratando solo un componente, si eso podrá reducir el riesgo de ataque cardiaco y apoplejía. Hablaremos de eso después que lleguemos a ese punto en el consentimiento.

El plan es si usted se inscribe en este estudio estaría involucrado entre 5 ½ y 8 ½ años. Sin embargo, (4:02) hay una mesa directiva de seguridad que revisa los resultados del estudio y si hay alguna razón para parar el estudio podría terminarse más temprano que el tiempo ya indicado. Esperamos tener 10.000 personas de los Estados Unidos y Canadá de 70 clínicas. La universidad espera tener 250. ¿Entonces que realmente va a ocurrir en este estudio si usted le toca ser un participante? Se empieza con una cita inicial donde se le tomara su historial médico, hablaran de sus problemas de salud en su pasado, revisaran la presión de su sangre, la azúcar en su sangre, y el colesterol para determinar si usted califica para este estudio. También tendrá un examen físico será breve tomaran un poco de su sangre como dos cucharaditas para el análisis de los riñones, lípidos y la función del hígado. También tomarán una muestra de orina (5:04) para el análisis/la búsqueda de proteína. Desde ese punto todos serán parte del estudio pero con la condición que participen también en el estudio adicional de colesterol, lípidos en la sangre o la presión de la sangre. Si usted está participando en la parte de la presión de la sangre, entonces su propio medico revisara el colesterol o si está participando en la parte de colesterol, entonces su propio medico revisara la presión de la sangre. Nosotros estaremos en comunicación con el doctor durante el tiempo del estudio, enviándoles los resultados e mantenerlos al tanto de lo que está pasando. STOP here – ask for comments

El grupo de tratamiento del azúcar en la sangre, hay dos opciones y una persona es seleccionado at aleatorio (como lanzamiento de moneda). Por ejemplo, cuando estamos lanzando la moneda, uno tiene la mitad de oportunidad de ser

seleccionado estar en el grupo intensivo y la otra mitad en el grupo regular. No tenemos opinión alguna sobre en qué grupo estará, aun usted no tiene opinión sobre a cual grupo desea estar. Entonces queremos estar seguros si usted estaría bien participar en cualquier grupo porque es una chance de 50-50 en participar en cualquier grupo. La meta intensiva es reducir el azúcar en la sangre más bajo de lo recomendado y la meta patrón es mantener el azúcar en la sangre a un nivel que es recomendado. Basado en el grupo que usted este practicando le cambiaríamos el tratamiento de diabetes. Como todos los medicamentos que estaremos usando en el estudio, son aprobados. Y el doctor y lugares que practican cuidado de medicina los utilizan al corriente entonces no es algo para examinar o algo no estudiado. Si le toca estar en la meta intensiva de la azúcar en la sangre, es probable que necesitara (7:00) mas tratamiento porque para reducir la azúcar en la sangre más bajo de lo recomendado se requiere dos medicinas por boca, insulina, y mucha comunicación con nosotros porque ajustares la insulina. También estaremos verificando el azúcar en su sangre frecuentemente, tendrá que tomar varias pastillas, insulina, pincharse el dedo hasta 8 veces al día que abarca mucho de tiempo. Queremos asegurar que usted entiende el compromiso que uno tomara al estar aleatorizado (como lanzamiento de moneda) al brazo intensivo.

La manera en como medimos los cambios del mantenimiento de diabetes es por el examen por nombre hemoglobina A1c. Este examen es como el promedio de la azúcar en la sangre en los últimos dos o tres meces. Si le toca estar él en grupo intensivo, la meta será mantener el A1c menos de 6% (8:03) este es algo que alguien sin diabetes tiene. Esto es algo más bajo de la práctica médica. Y si esta en el grupo patrón, la meta seria mantener su A1c en medio de 7 a 7.9 cuál es el promedio de la azúcar en la sangre a 160 (el numero en la cajita que cheque el azúcar en la sangre) si esta pinchándose el dedo. Este número es un poco bajo de la meta en la práctica general. Pero sabemos que en experiencias del pasado cuando se baja el A1c de 8 y 9 al tiro de 7 reduce el riesgo de complicación de los ojos, riñones, y nervios. Pero la pregunta es que si bajamos el número más puede haber un riesgo de hipoglucemia (azúcar en la sangre baja). Enconches queremos encontrar el balance **(9:02)** de lo mejor. Ya sabemos que la meta intensiva de 6% o menos en comparación a la meta patrón de 7.5% tiene un riesgo poco alto para la complicaciones de diabetes como enfermedad ocular, riñones y de la función

anormal de los nervios o neuropatía. Personas (también que ustedes conocen) lo describen como una sensación de quemasen en los pies. Por el otro lado, ya se sabe que un A1c menos del 6% aumenta el riesgo del desarrollo de la azúcar en la sangre gravemente bajo. Y eso causa aumento de peso. Entonces si el A1c bajo es mejor o el Ac1 alto es mejor para proteger la enfermedad del corazón es lo que realmente lo ACCORD está tratando de establecer. Y para aquellos en el grupo patrón, ACCORD recomendara tratamiento y tomara mayor acción si el A1c sube más de 7.9% **(10:05)** y si el A1c baja menos de 7% le vamos a quitar insulina o el medicamento para mantenerlo en el meta al tiro. En el grupo intensivo, si el A1c es por un pocito arriba de 6%, le aumentaremos el tratamiento. Entonces la importancia de este estudio es manteniendo una distinción de los dos grupos porque si no tenemos una distinción no podremos contestar la pregunta. Es de suma importancia que usted está comprometido en cumplir con lo necesario para llegar a las A1c metas y por supuesto, le ayudaremos con eso. STOP here – ask for comments

Según los resultados de la presión de la sangre y colesterol, tendrá que participar en uno de los brazos de tratamiento del estudio, ya sea el tratamiento de la presión de la sangre o de lípidos. Y sabemos que el tratamiento de la presión de la sangre puede prevenir la enfermedad del corazón, riñón, y apoplejía. También hay evidencia que cuando la presión de la sangre es reducida más de lo que suele ser normal puede prevenir (prevent/evitar) enfermedad del corazón o apoplejía para aquellos con diabetes. Como no tenemos estudios en escala grande que comprueben esto, eso es lo que queremos hacer. Si usted está en la porción del estudio de la presión de la sangre, estará seleccionado como el lanzamiento de moneda al grupo de la meta intensiva o patrón de la presión de la sangre. El doctor que le toque en este estudio identificar (choose) los medicamentos que serán mejor para usted, según los efectos secundarios o otras preocupaciones que usted tiene. Le encontraremos el mejor tratamiento que funcione lo mejor para usted. Repetimos que estamos usando medicamentos ya aprobados utilizados en la práctica general. La distinción es las metas de la presión de la sangre serán diferentes según el grupo donde usted este. **(12:00)**

Para aquellos en el grupo de tratamiento de los lípidos en la sangre, ya se sabe que reduciendo el colesterol de la sangre puede prevenir/evitar enfermedad del corazón y apoplejía. También hay evidencia que cambiando otros lípidos de la

sangre y reduciendo los triglicéridos o la grasa en la sangre y aumentando el HDL-colesterol conocido como el colesterol bueno, puede prevenir la enfermedad del corazón y apoplejía en personas con diabetes. Pero queremos examinar esto cuidadosamente. Entonces si usted es seleccionado para la parte del estudio de lípidos, el medicamento si esta tomado alguno ahora se lo quitaran y le darán el medicamento para el estudio. El tratamiento será con una medicina por nombre "statin". El trabajo principal de statins es reducir el colesterol malo. Para esta parte, tenemos mucha evidencia pacientes con diabetes tomando statin verdaderamente tienen poco riesgo de enfermedad del corazón. Como esa es la practica general, definitivamente queremos mantenerlos allí pero la pregunta es si hay un mejor beneficio cuando agregamos el segundo medicamento que reduce la grasa en la sangre y eleva el colesterol bueno. Todos estarán tomando el medicamento statin por nombre simvastatin. De allí la mitad estarán en el grupo de fenofibrate; que reduce los triglicéridos y eleva el colesterol bueno (HDL). Y la otra mitad estarán en el grupo de placebo; que no contiene medicina. Es de suma importancia que esté tomando el medicamento fenofibrate o placebo durante todo el estudio para poder determinar al final y actualmente saber si hay diferente outcomes para aquellos tomando el medicamento verdadero en comparación a los que están tomando el placebo. Si el colesterol se mantiene demasiado alto, tendremos que ajustar la dosis de simvastatin para poder llegar a la meta recomendada. **(14:06)** Sabemos que el fenofibrate posiblemente puede dañar los riñones entonces estaremos analizando la sangre para revisar la función del riñón. Si los resultados no son normal, entonces la dosis de feofibrate o placebo será reducido o se la quitaremos. El médico continuara en evaluar la función de los riñones.

Esa fue mucha información. ¿Quiero saber si tienen preguntas sobre el estudio de la diabetes, la presión de la sangre o los brazos de colesterol? Si no hay preguntas, entonces le seguiremos. STOP here – ask for comments

Encontramos en este estudio un componente genético. El estudio genético será como parte de este estudio y si usted desea puede ser voluntario para esta porción del estudio. Porque uno está participando en este estudio no está automáticamente en el estudio genético. (15:02) Pero si usted desea en participar, entonces almacenaremos algunas muestras de sangre para hacer el

análisis genético. Explicaremos eso en un momento cuando lleguemos a esa parte del consentimiento.

Las citas de consulta, este estudio se demorara por varios años y requiere un compromiso de largo plazo. Las consultas pueden ser con frecuencia mensuales o a lo mínimo cada cuatro meces. Sin embargo, usted estará viniendo muy seguido y recibirá llamadas durante el tiempo que no esté aquí. Repetimos, queremos asegurarnos que usted está bien con la idea que estará participando por un tiempo larguísimo. También depende en cual grupo este está participando tendrá que venir con más o menos frecuencia. Pero típicamente lo mínimo será una consulta cada cuatro meses y lo máximo seria consultas mensuales. En el primer año tomaremos muestras de sangre cada cuatro meses. Después de ese año tomaremos muestras de sangre cada año. Estas muestras son análisis típicos en la práctica general de medicina que pasaremos al doctor que usted ve.

Se es seleccionado a la meta intensiva de la azúcar en la sangre, como les dije anteriormente, tendrán análisis de sangre en la clínica con más frecuencia donde las consultas serán cada mes por los primeros cuatro meces y cada dos meces después de los primeros cuatro meces. Y estaremos comunicándole a lo mínimo cada mes para revisar con usted como van las cosas.

Si está participando en el estudio de colesterol, el análisis del colesterol en su sangre será cada cuatro meces durante el primer año. Después del primer año será cada año hasta que terminamos el estudio. También tomaran una muestra de sangre cada cuatro meces durante el estudio para chequear la función de los riñones. Si no está participando en el estudio de colesterol, el análisis de colesterol en su sangre será cada año. Mencionaremos monetariamente, que como parte del cuidado de diabetes, se espera que cheque (17:06) la azúcar en su sangre. Y para cumplirlo, le daremos lo que es necesario para el chequeo casero de la azúcar en la sangre. También tomaremos una muestra de orina en la cita como base de referencia y cada dos años después de ello para examinar la medida de la función del riñón mediante la proteína y creatinina en la orina. También haremos un EKG que viene siendo una grabación de la actividad eléctrica del corazón en la cita inicial, en la base de referencia y después de cada dos años. También examinaremos los ojos cada otro año.

También tiene usted una entre cinco chancas. Por ejemplo, entre un grupo de 100 personas, 20 personas serán seleccionadas en llenar cuestionarios sobre la cualidad y actividad de vida y también sobre la dieta y el nivel de actividad física. Entonces estos cuestionarios van a tomar más tiempo como una hora. Las llenaran al principio del estudio, en uno año y tres años, y en la visita del cuarto año. STOP here – ask for comments

Aun y otro como un sub-estudio. Una porción más pequeña de las personas en el estudio serán vigilados estrechamente sobre los costos del cuidado de salud. Entonces, si es internado al hospital, le preguntaremos que nos dé permiso para obtener su registro medico.

Hay algunos procedimientos y exámenes medícales que se recomiendan para personas con diabetes que no son parte de este estudio, por eso es de suma importancia que usted informe al doctor de su familia o la clínica de recibe cuidado medica a lo mínimo cada año. Recomendamos que no reemplace los siguiente exámenes con los que haremos: examen ocular con el oculista, examen de los pies, vacunas, inyecciones de la influenza, vacunas de la gripe y neumonía, EKGs. Por ejemplo, el examen que haremos de los ojos no es igual como en una clínica, es más como un estudio. Entonces tendrá que hacer citas anuales sobre la prevención de enfermedades (patrón health assesments) con el doctor de su clínica.

Durante el estudio el coordinador central o uno de los representantes les llamara para preguntarles sobre su participación en este estudio. Por ejemplo, le preguntaran si están teniendo problemas en tomar el medicamento, o como se sienten, o si han necesitado ser hospitalizados por cual quiera razón, donde fue hospitalizado y porque. STOP here – ask for comments

Entonces como estudio de largo plazo y muchos tratamientos consiste de varios riesgos en participar. Yo quiero que tomen en cuenta cuáles son esos riesgos. ¿Entonces, cuáles son? Bueno, como aún no se sabe cuáles son los riesgo y peligros potenciales para un bebe antes de nacer, queremos saber por parte de usted que no se embarazara durante este estudio (20:02) Si usted es una mujer, le pedimos que use un método anticonceptivo confiable durante este estudio. Si no está dispuesta hacerlo, entonces le pedimos que participe en este estudio. Pero si hay varios métodos anticonceptivos confiables cual están mencionados aquí en

el formulario de consentimiento. Y si ya está embarazada no puede participar en este estudio. Lo que si pedimos de cada mujer que es sexualmente activa o tiene la edad para concebir hijos e hijas, es que tome una prueba de embarazo 10 días después de la regla.

También estaremos tomando muestras de sangre en este estudio. Cada vez que tomamos muestras de sangre corre el riesgo de infección, dolor o mareado. Estoy segura que muchos de ustedes han dado muestras de sangre que han sido incomodas. También le pedimos que haga el chequeo de la sangre y de nuevo le daremos lo necesario para hacerlo y podría ser incómodo. Entonces quiero se tome en cuenta de la posibilidad en hacer el chequeo hasta ocho veces al día. Si es seleccionado a la meta intensiva de la azúcar en la sangre, tiene uno chanca grande en tendrá que chequear el azúcar en la sangre hasta 8 veces diarios. Después de eso haremos un análisis de los números de glucosa para poder hacer mejores recomendaciones. La razón por la frecuencia de los chequeos es para poder modificar el tratamiento de diabetes en una manera saludable (health) y alcanzar la meta más baja de azúcar en la sangre sin causar mucha hipoglucemia o azúcar en la sangre demasiado baja. Cuando estamos hablando de riesgos de hipoglucemia o azúcar en la sangre demasiado baja; esto ocurre cuando está haciendo mucho ejercicio o cuando está comiendo menos que resulta en ciertas síntomas. **(22:09)** Síntomas ligeras incluye; sentir hambre, ansiedad, mareo, sudando, cansancio, confundido o temblores, y sentir que el corazón palpita rápidamente. Estas cosas pueden hacerlo sentirse incómodo y como ya sabemos que en el grupo intensivo tendrán mayor oportunidad de tener estos sistemas. Y queremos darle a conocer para que no le caiga como sorpresa. La mayoría de las personas no todas que han tenido diabetes hasta cierto punto han tenido estas síntomas. Entonces, si es nuevo para usted quiero darle a conocer como se sentirá.

Hipoglucemia severa o azúcar en la sangre demasiado baja puedo causar falta de conocimiento, y si esto ocurre cuando está conduciendo un vehículo o mecanismo de operación le resulta sería una herida terrible y hasta peligro de vida. Pero de nuevo repetimos que se cheque el azúcar en la sangre seguido para pronosticar los patrones y tratar de evitar lo más posible. En raros casos la hipoglucemia puede ser severa que requiere tratamiento de emergencia u hospitalización y la azúcar en la sangre demasiado baja puede causar daño al cerebro, coma, y

muerte. Lo cual esto puede pasar en un paciente tomando medicamento para reducir el azúcar en la sangre pero es más común entre aquellos que están en el grupo intensivo tomando insulina. Típicamente jugo o tabletas de glucosa conocidas como pastillas de azúcar pueden elevar la azúcar cuando siente estos síntomas pero cuando la azúcar está severamente baja a veces es necesario que los médicos vengan a casa y pongan suero o glucosa directamente en las venas **(24:01)** o glucagón que es un medicamento que rápidamente aumenta el azúcar en la sangre. Este riesgo es muy bajo pero sí lo es posible. En cualquier grupo del tratamiento de la azúcar en la sangre, la salud será lo más importante cuando hacemos los ajustes en el cuidado de la azúcar. Basado en estudios previos la estimación en el grupo intensivo es que seis de 100 participantes tendrán complicaciones como estar en el hospital o ir a la sala de emergencia y en el grupo estándar como 2 participantes tendrán ese tipo complicaciones cada año. En cualquier grupo los doctores y enfermeras de ACCORD tomaran acción para reducir el riesgo de hipoglucemia y si es que eso ocurre seguido o en una forma severa. Es por eso la importancia de comunicación frecuenté. En el otro lado, los participantes en el grupo patrón podrán tener un riesgo más alto de complicaciones como los ojos, enfermedad de los riñones o función anormal de los nervios en relación a diabetes (25:04) y la estimación de complicaciones cada año en el grupo intensivo es uno entre 100 participantes y en el grupo patrón será 1,5 participantes entre 100 que se presenten con esas complicaciones cada año. Si es seleccionado estar en el grupo intensivo de la presión de la sangre puede llegar a tener presión de la sangre demasiado baja. Típicamente las personas se sienten mareos, fatigados, o con desmayo entonces re recomienda sentarse o moverse lentamente para aliviar esos síntomas. Pero si tiene esas síntomas nuestro desello es que nos diga inmediatamente para ajustar su tratamiento.

Ahora voy hablar de cada medicamento que podríamos usar en este estudio; los tratamientos de la azúcar en la sangre, el tratamiento de la presión de la sangre y los tratamientos del colesterol. Todas estas medicinas que vamos a discutir son las que usamos diariamente en la práctica médica. Lo que ya se sabe es que cualquier medicamento consiste del riesgo de alergia que si no lo ajustamos de inmediato pone la vida en peligro. De nuevo si usted siente efectos secundarios, déjenos saber de inmediato.

Cuando esto ocurre en vio se tiene que explicar todos los medicamentos utilizados en cada brazo del estudio. Como es una lista demasiado larga que tomaría de 20 a 25 minutos de explicar vamos a referir las páginas del formulario de consentimiento.

¿Entonces cuales son los beneficios? Como no sabemos si el tratamiento do ACCORD como estar en el grupo intensivo, estar en el grupo patrón, estar en el grupo de presión en la sangre, o estar en uno de los dos brazos del grupo de colesterol será beneficio personal para usted. Pero lo que sí sabemos es que al coleccionar la información del estudio será muy importante para el tratamiento de la diabetes en el futuro y posiblemente en la misma generación y para solo saber la mejor manera en cómo tratar el diabetes tipo 2. No tendrá cargo para cualquiera de las pruebas y procedimientos necesarios para este estudio, o las cosas necesarias para chequear el azúcar en la sangre, consultas, análisis en el laboratorio y le informaremos al doctor quien lo atiende de los resultados. No se le paga por su participación en este estudio pero todo lo necesario para chequearse la azúcar en la sangre será gratis.

¿Y cuáles son las alternativas? Bueno como estaremos usando medicamento utilizados en la práctica médica, puedo obtener el mismo tratamiento con el médico que lo atiende. Esa es una alternativa que el médico le den el tratamiento de diabetes, presión de la sangre y colesterol en adición a la nutrición (dieta) ejercicio, bajo de peso todos en total como tratamiento del diabetes.

Y por parte de este estudio, tendrá usted la oportunidad de consultar (work/trabajar) con nuestro dietético y los educadores en diabetes para hacer cosas similares.

Si en el caso de que tenga una herida relacionada con este estudio, no es probable que sufra problemas principales de salud por participar en este estudio pero siempre hay un riesgo pequeño en tener complicaciones graves de salud. Si eso ocurre, el tratamiento estará disponible, incluyendo primeros auxilios, tratamiento de urgencia y los cuidados de seguimiento según sea necesario. Estos costos serán mandados a cobrar con la seguranza de salud que usted tengo como no son costos cubiertos por el estudio.

Con respecto a confidencialidad, queremos proteger su privacidad. Entonces cualquier información que obtengamos de usted durante este estudio será

tratada con estricta confidencia donde se le asignara un número de código si decide participare en este estudio entonces no utilizaremos un nombre o cualquier otra información asociado con su nombre. Sin embargo, su nombre y número de seguro social y números de Medicare serán registrados y almacenados de forma centralizada para ayudar a la llevar un registro del estudio de cualquier enfermedad que usted puede experimentar. Y si quiere ordenar lo cosas gratuitas que son necesarias para chequear el azúcar en la sangre necesita proveer esa información para nosotros poder cobrarlos a la seguranza medica que tenga usted como Medicare o cualquier otra que usted tenga. **(45:02)** Y si no tiene Medicare o cualquier otra entonces este estudio lo pagara. Cuando publicaremos los datos de este estudio no habrá nada que lo identifique en la publicación. Al final del estudio, todos los formularios que contienen su nombre u otros datos de información estarán guardados bajo llave hasta cinco años. Y solamente los médicos del estudio y los asociados que apoyan al médico del estudio tendrán acceso a los documentos. Después de los cinco años, los documentos serán destruidos. STOP here – ask for comments

Orina, sangre y / o materiales tomados de usted durante este estudio se considerará donación de su parte para la investigación médica. Y estos materiales también pueden ser compartidos con la NHLBI al final del estudio, de nuevo sin información de identificación personal. También pueden ser compartidos con otros científicos que cumplan con los requisitos del NHLBI para poder aprender más de diabetes y los problemas relacionados con ello. Las compañías farmacéuticas que han contribuido las drogas, y en algunos casos dinero, para el estudio ACCORD también se compartirán los datos del estudio y sin ninguna información de identificación personal.

Es particularmente importante que usted sepa que ACCORD se ha concedido un certificado de confidencialidad por parte del Gobierno Federal de los Estados Unidos para asegurarse la mejor manera de proteger su privacidad. Esto significa que los investigadores de ACCORD no pueden ser obligados a decir a nadie no conectado con el estudio acerca de su participación. Esto incluye los tribunales y la policía. Los investigadores sólo podrán divulgar información si usted lo solicita.

Hay algunos límites a la capacidad del investigador para mantener confidencialidad. Si nos enteramos que al mantener su información privada lo

pondría en peligro inmediato o poner a otra persona quien conocemos en peligro inmediato, entonces vamos a tener que decirle a las agencias apropiadas para protegerlo o proteger la otra persona.

Entonces la participación en este estudio es completamente voluntaria. Usted puede optar en cualquier momento no participar o puede retirarse del estudio no dará lugar a ninguna sanción o pérdida de beneficios si usted decide no continuar la participación en este estudio el doctor del estudio si es necesario también tiene el derecho de quitarlo para que no participe en el estudio. La cause de ser quitado es porque ha tenido una reacción inesperada, o ha fallado en cumplir con la letra de las instrucciones, o porque el estudio entero se termino antes de tiempo.

Entonces toda la información nueva que colectemos del estudio que pueda afectar su salud, el bienestar o la voluntad de permanecer en el estudio ACCORD será compartida con usted. Y los resultados de las pruebas del laboratorio y medidas de la clínica serán compartidas con usted para que las muestre con el médico que lo atiende.

¿Ahora, que preguntas tiene usted para mí? Es mi deseo repetir las áreas que les son claras, para asegúranos que usted entiende lo que esperamos de usted. Me gustaría que usted me esplique en propias palabras en qué consiste lo que le estamos pidiendo que hagan. STOP here – ask for comments

Quiero revisar los números telefónicos para cuando en cualquier momento usted tenga una pregunta y se siente mas cómodo en hablar con alguien que no está involucrado en este estudio, tenemos la Línea de Ayuda de Investigación Fairview, con los datos más abajo. Y si quiere hablar con la investigadora principal, Dr. Seaquist, sus datos también están allí.

Ahora hablare brevemente de los estudios genéticos. Repetimos, los estudios genéticos son una para en adición de este estudio. No tiene que participar en el estudio genético para participar en el estudio principal de ACCORD. Una de las metas de ACCORD es para examinar su material genético y la relación de los efectos de los tratamientos. Si usted decide participar voluntariamente en los estudios genéticos necesitaran una muestra de sangre (aproximadamente 1 cucharadita) para obtener el ADN de las células sanguíneas. La ADN es simplemente el material genético en las células sanguíneas. ¿Y que pasara con las muestras de ADN? Bueno examinaremos la ADN directamente o utilizarla para

crear una muestra de tejido vivo (o línea celular) cual viene siendo para los investigadores un suministro ilimitado de ADN que pueden utilizar en el futuro sin tener que tomar más muestras de sangre de usted. Y no es un clon humano pero es simplemente mas células de la muestra que nos dio **(50:03)** des de un principio.

Nosotros compartiremos las muestras de ADN con otras instituciones universitarias. Con su permiso, el Laboratorio Central ACCORD puede compartir muestras de ADN con los investigadores que participan en el estudio de ACCORD. Si usted da permiso, las muestras también se pueden compartir con otros laboratorios de investigación que estudian la genética de la diabetes tipo 2 y enfermedades del desarrollo de corazón y vasos sanguíneos, de otras enfermedades importantes, condiciones de salud o factores de riesgo. Los científicos de estos laboratorios recibirán el ADN sin ninguna información de usted en ello.

¿Y como serán utilizados estas muestras en el futuro? La información obtenida de la investigación en su línea de células o ADN puede ser utilizado para desarrollar nuevas maneras de detectar o tratar enfermedades graves. STOP here – ask for comments

¿Y como mantendrán esta información genética privada? Sólo el gerente de los datos del estudio de ACCORD tendrá acceso. Ningún otro individuo, incluyendo al cónyuge, padres, hijos, el médico que lo atiende o el empleador tendrá acceso a la muestra almacenada o información obtenida de la muestra almacenada. Al final del estudio, las muestras se pueden compartir con otros investigadores, en determinadas condiciones, sin ningún tipo de información que lo identifique.

¿Cuánto tiempo almacenaran las muestras de ADN? Mantendremos la muestra hasta que no tenga valor científico. Si, en cualquier momento durante el estudio, usted decide que la muestra de ADN no sella almacenada por más tiempo, la muestra será destruida.

¿Quién es el dueño de la muestra? Al marcar "sí" al final de este documento, usted se ofrece voluntariamente para proveer muestras genéticas para propósitos de investigación médica. Su línea de células o ADN no la venderemos a nadie ni a instituciones o empresas para obtener ganancias financieras o beneficios comerciales sin su consentimiento. Sin embargo, ni usted ni sus herederos como

los hijos e hijas o conjugue recibirán el dinero de cualquier descubrimientos o invenciones realizadas con la información y / o especímenes que usted proporciona.

¿Recibirá usted los resultados del estudio que utilizaron las muestras? Como no es un examen médico y no se utiliza para darle información específica sobre la salud o genes propios, no le darán información de los resultados de la investigación realizada sobre la muestra de su sangre genética. Sin embargo, un examen genético puede ser desarrollado después de haber estudiado muestras en el estudio de ACCORD. Si hay alguna información nueva acerca de las pruebas genéticas para la diabetes tipo 2 en relación al corazón, enfermedades de venas sanguinas u otras condiciones de salud, le notificaremos por medio del médico del estudio ya sea si esta información puede ser importante para usted o la familia. Y no hay ningún costo para usted en todo esto. Entonces si usted decide participar en la porción genética tiene tres opciones.

Una es marcar que "Si, estoy de acuerdo en participar en la parte genética de ACCORD y permitir que mi muestra genética sea desarrollada para estudios genéticos en el futuro" o tiene lo opción de estar de acuerdo en participaren en la porción genética pero no en tender una línea de células o ADN desarrollada o puede decidir en no participar en la porción genética.

También puede elegir cuales condiciones de estudios podremos hacer con la muestra genética. Si desea participar, puede elegir una enfermedad u otra condición de salud o factores de riesgos. También puede elegir que sella solamente estudiada para genes relacionados a la diabetes, presión de la sangre, anormales del colesterol en la sangre, enfermedad del corazón, otras enfermedades del corazón, enfermedad del riñón u otros factores de riesgo de enfermedades del corazón. Si está de acuerdo en participar en la parte genética, entonces queremos que cheque una de los siguientes investigadores quien tendrá acceso a las muestras. Usted puede elegir que las muestras genéticas sean utilizadas en la investigación por los investigadores de ACCORD y por otros científicos/investigadores que cumplan con las normas y procedimientos del National Heart, Lung and Blood Institute (el instituto nacional del corazón, pulmón y sangre) o que las muestras genéticas sean utilizadas **SOLO** en estudios por los investigadores de ACCORD.

Esto fue mucha información y sé que tienen preguntas sobre esto. Estoy aquí para contestar las. Ahora que hemos revisado el formulario de consentimiento juntos quiero que tomen tiempo para pensarlo antes de firmar. Este es un compromiso grande para usted. Para su bienestar, quiero estar segura que usted estará bien en seguir todos los requisitos de este estudio antes de empezarlo. Vuelvo a repetir, estoy aquí para contestar sus preguntas y si puede explicarme lo que usted entendió de lo que se requiere para poder comprender que si entendió todo el aspecto del estudio.

Appendix W

ACCORD Consent Transcript Revised English

ACCORD Consent (55:07)

Well welcome thank you so much for coming to talk about the ACCORD study with us. I know we talked about the study over the telephone and I kind of summarized it and sent you out the consent form and I just want to go through it with you in detail with you today so you can get a good sense of whether this is something you'd like to participate in or not. Did you have a chance to look through the consent form that I sent you?

OK great! I'm just going to summarize – the whole purpose of this study is that we're trying to figure out the best way to treat people with Type 2 diabetes to reduce the risk of heart attack and stroke. Heart attack and stroke we know is two to four times greater among people with diabetes compared to those in the general population (1:05) So it's a pretty important question, if we can find a way to reduce that risk that will have very good implications for the future of treating diabetes. So we've invited you to join in this study and determine if you are eligible for this study. This study is sponsored by the National Heart, Lung and Blood Institute, it is part of the United States government and that just means that the money for this study comes from the government so taxes that we pay are going to support this study. The main doctor that's involved in this study and who started the study is Dr. Seaquist and she is a diabetes specialist here at the University. So we'll start off by going through the consent, please interrupt me at any point if you have questions or something does not seem clear because I'm happy to answer them along the way (2:06)

So we know that Type 2 diabetes is very common in North America and people with Type 2 diabetes have a higher chance of getting heart disease and stroke than people without diabetes. And so again, the purpose is to find the best ways to lower that risk in people with Type 2 diabetes. The ACCORD study is going to answer three questions. In diabetes we know that the level of blood sugar is too high so we want to know if lowering the blood sugar to a level that is normally targeted the way you would see your doctor right now compared to getting it lower than that, if that will reduce your risk of having heart attack and stroke. We know that people with diabetes often have high blood pressure as well and so the second question is to determine if lowering blood sugar to a lower level that's currently used in clinical practice, will that also reduce your risk of heart attack and stroke. And the third question is, we know that many people with

diabetes also have problems with their blood cholesterol or lipids, that's the fat that is in your blood and so we want to know if we treat a couple different components of your blood lipids compared to treating only one component, if that will reduce your risk of heart attack and stroke. And I'll go through that in a little more detail later in the consent process.

So the plan is if you were to enroll in the study you would be involved in the study for between 5 ½ years to 8 ½ years. However, (4:02) there's a safety monitoring board that reviews the results of the study and if they see any reason to stop the study earlier it could end earlier than that. We hope to recruit about 10,000 people across the U.S. and Canada from about 70 different clinics and the University of Minnesota site is hoping to have about 250. So what is actually going to happen if you participate in this study? We start off with a screening visit, that's when you take your medical history, talk about medical problems you've had in the past, look at your blood pressure, your blood sugars, and your cholesterol and we'll see if you would be eligible for this study. You'll have a short physical exam, a little bit of blood would be taken, about two teaspoons to check your kidney, liver and cholesterol (5:01) and some urine would be collected also (5:04) to look for protein. Now everybody would be involved in the diabetes part of the study but then we would also want you to be involved with either the cholesterol or the blood lipid portion or the blood pressure part of the study. So if you were involved in the blood pressure part then your own doctor would manage your cholesterol and if you were involved in the cholesterol part then your own doctor would manage your blood pressure. And we do stay in communication with your doctor throughout the entire study sending blood test results and keeping them up to date on what's going on.

The blood sugar treatment group, there are two options and it's a random assignment so let's say for instance we're flipping a coin there is half a chance that you would be in the intensive group and half a chance that you would be in the standard group. We don't have any say in which group you would be involved in and you don't have any say so we really want to be sure that you feel comfortable in either group because it is a 50 – 50 chance that you would go in either group. The intensive goal would be to lower your blood sugar lower than is currently recommended and the standard goal is to try to keep your blood sugar at a level that is similar to what is currently recommended. We would change your diabetes treatment based upon which group you are assigned to. But all of the medications that we would be using in the study are currently approved diabetes medications that your doctor and all medical providers are using at this time so it is nothing that is experimental or untested. So if you are randomized to the intensive blood sugar goal its very likely that you would need (7:00) more treatment because to get to a

lower blood sugar goal it often requires two oral medications, usually insulin and lots of contact with us because we will be adjusting your insulin and then frequent blood sugar monitoring so you may have to take several pills, take insulin, do finger stick testing up to 8 times a day so it can be quite involved so want to make sure you understand the commitment that would be involved if you were to be randomized to the intensive arm.

The way we measure how your diabetes management is going is by a test called a hemoglobin A1c. This test is like an average of your blood sugar over the last two to three months. If you are in the intensive treatment group the goal would be to keep your A1c less than 6% (8:03) which is what somebody without diabetes has as far as an A1c. This is much lower than what we are usually targeting in clinical practice and if you're in the standard group the goal would be to keep your A1c somewhere between 7 and 7.9 which averages out to a blood sugar of 160 if you are testing on your finger sticks. This is a little bit lower than what is usually achieved in clinical practice but we know from previous experience that bringing the A1c down from the 8 and the 9 range into the 7 range really reduces your risk of having eye, kidney, and nerve complications. But the question is if we go lower than that there is always a risk of having more of hypoglycemia, which is also known as low blood sugar so we want to try find the balance (9:02) of what's best. We know that compared to the intensive target of less than 6% the standard target of 7.5% has a little bit higher risk for some diabetes complications and these include eye disease, kidney disease and abnormal nerve function or neuropathy. Some people describe that as a burning sensation in their feet, you may know other people who've experienced that. On the other hand, we know that getting an A1c of less than 6% can increase your risk of developing serious low blood sugars and can cause some weight gain and so whether the lower A1c is better or the higher A1c is better as far as protecting against heart disease is really what we ACCORD is trying to find out. And in the standard group ACCORD will recommend treatment and take further action if your A1c goes higher than 7.9% (10:05) and if your A1c drops below 7% we may be removing some insulin or some medications so that it is in the targeted range. In the intensive group if your A1c is even slightly over 6% we will increase your treatment. So the importance of this study is really keeping a difference between the two groups because if we don't have a difference we won't be able to answer this question. So it's very important that you're willing to commit to doing everything needed to achieve the A1c targets and we'll help you along with that of course.

Depending on your initial blood pressure and cholesterol results you will be asked to participate in either the blood pressure or the lipid treatment arms of the study. We know that blood pressure treatment can help prevent heart disease, stroke, and kidney disease.

And there is some evidence that lowering blood pressure further than what's currently recommended can help prevent heart disease or stroke in people with diabetes. But we don't have any large scale studies that have ever been done to show that so that's what we want to do. If you're in the blood pressure portion of the study again you will be randomly assigned, again like the flip of a coin, to either the intensive or standard blood pressure target. Your study doctor will choose the medications that would be best for you based on side effects or any concerns that you have and we'll find the best treatment that works well for you. Again, we're using all standard, approved medications that we use in clinical practice; it's just that the blood pressure targets will be different depending on which group you are assigned to. (12:00)

In the blood lipid treatment group we know that lowering blood cholesterol can help prevent heart disease and stroke. There's some evidence that changing other blood lipids by lowering triglycerides or your blood fats and raising your HDL-cholesterol which is also known as the good cholesterol, that might prevent heart disease in people with diabetes. But we also need to test this a little more carefully. So if you are eligible for the lipid part of the study, your current medication, if you are on any, will be stopped and then we'll change you to the study medication. You'll be treated with a medication known as a "statin" and statins mainly work at lowering your bad cholesterol. And we do have a lot of evidence that patients taking statins that have diabetes really have a lower risk of heart disease so we know that's the standard practice so we definitely want to keep you on that but the question is if we add a second medication that lowers your blood fats and raises your good cholesterol, if that will give you more benefit. And so everybody will be on the statin medication, known as simvastatin, and then half of you would be assigned to the fenofibrate group, which is the medication that lowers your triglycerides and raises your HDL and half of you would be assigned to a placebo, which is a pill that does not contain any medication. But it's very important that you take either the fenofibrate or the placebo for the entire study so that in the end we'll actually know if those taking the real study drug compared to those taking the placebo had different outcomes. If, during the study, your cholesterol remains too high we'll have to adjust the dose of the simvastatin to target your cholesterol to the recommended level. (14:06) We do know that fenofibrate could possibly harm the kidney so we'll be doing frequent blood tests just to watch your kidney function. If your results are not normal then your dose of fenofibrate or placebo will be reduced or stopped and after your dose is reduced or stopped, your doctor will continue to monitor your kidney function.

So that was a lot of information. Can I ask if you have any questions about the diabetes, the blood pressure or the cholesterol arms of the study? And if not then I'll keep going.

So there is a genetic component. Genetic research will be done as part of this study and you may if you wish volunteer for the genetic portion of the study. Just because you are in the study does not mean you automatically have to be in the genetic component. (15:02) But if you wish to participate, then we will store some of your blood samples to look at some genetic analysis. And we'll talk about that in more detail a little bit further in the consent.

So the visit schedules, this is a long study, it's going to be over years and it's a long time commitment. Visits can be as frequent as every one month to as little as every four months. But you will be coming in quite often with phone calls in between. And so again we just want to make sure you feel comfortable with the idea that you're going to be in this for a long time. Depending on which group you are in, there may be more frequent or less frequent visits but in general the least would be every four months and the most would be every month. We'll do blood draws every four months for the first year and then once a year after that and they are all standard labs that we would be measuring in clinical practice and we will again share those with your own doctor.

If you are assigned to the intensive blood sugar goal, as I said you will have more frequent blood sugar testing in the clinic and the testing will range from once a month during the first four months to every two months thereafter but we will be contacting you at least monthly to check in how things are going.

If you are in the cholesterol study your blood cholesterol will be measured every four months during the first year and every year after that until the end of the study. You'll also have blood drawn every four months throughout the study to check your kidney function. If you are not in the cholesterol study you will have your cholesterol measured every year. And as part of diabetes management you will be expected to check (17:06) your own blood sugar as discussed later. All we will provide you with are the test supplies and test strips in order to do that. Some urine will be collected at the baseline visit and every two years thereafter so it can be examined for protein and creatinine which is a measure of your kidney function. And we'll also do an EKG which is a recording of the electrical activity of the heart at the first visit, at baseline and then every two years after that. And we'll do an eye exam every other year.

So you also have a one in five chance, so if there were 100 people then 20 people would be chosen to complete questionnaires about your quality and activities of life and then also about your diet and physical activity levels. So these questionnaires can take a little bit of time to fill out, about an hour. We'll ask you to complete them at the beginning of the study, at one and three years, and at the four year visit.

And there is another, sort of sub-study. A smaller portion of people may be asked to participate in a group where healthcare costs will be monitored. And then if you are admitted to the hospital, then we would ask for your permission to obtain any medical records.

There are certain medical procedures and tests that are not part of the research study that are recommended in general for people with diabetes and so it's very important that you still follow-up with these with your primary care physician or provider on at least a yearly basis. We recommend eye exams with an eye doctor, foot exams, getting vaccinations, flu shots, flu and pneumonia vaccinations, EKGs and we don't replace these with our exams. So the eye exam we conduct (19:00) is not a clinical exam, it's more of a research exam so we still ask that you follow up with your primary doctor and have your standard health assessments done every year.

During the course of the trial the central coordinating center or one of its representatives may contact you about your participation in the trial, for example you may be asked if you're having any trouble taking any of your medications and you may be asked how you're feeling or whether you've been in the hospital for any reason or where or why you were hospitalized.

So with such a long study and many treatments there are several risks of participating in the study and I want you to be aware of those. So what are the possible risks? Well, because we do not know the risks and potential harm to an unborn child we really want to make sure that you will not be becoming pregnant in this study (20:02) if you are a woman and so we ask that you use a reliable method of birth control through the study or if you're not willing to do that than we would ask that you not participate in this study. But there are several reliable methods of birth control and those are listed in the consent form here. If you are a pregnant woman you can't participate in this study and we just would require a pregnancy test at least 10 days after your period if you are sexually active and you're at the age where you could have children.

So we are also going to be doing several blood draws in this study and anytime we are drawing blood there is a risk for infection, risk for pain, and feeling light headed or faint. I'm sure most of you have had blood drawn but sometimes it can be uncomfortable. We also ask that you do finger stick measurements of your blood sugar level and again we are going to be providing the test strips and the testing supplies needed but it can be uncomfortable and when you are asked to possibly test eight times a day, that's something I just want you to keep in mind, that that's a possibility. If you are assigned to the intensive blood sugar goal there is a good chance that you'll be asked to do up to

eight times a day and then we review your glucose values and then we're able to better make adjustments. So the reason we want you to test so frequently is so we can most safely change you're diabetes treatment so that we can achieve the goal of the very low blood sugar readings without causing too much of hypoglycemia or low blood sugar. When we're talking about risks of hypoglycemia or low blood sugar, this can happen when you are doing more exercise, you're eating less and certain symptoms can occur when that happens. (22:09) Mild symptoms can include feeling hungry, anxious, dizzy, light headed sometimes you're sweating, feel very tired, you can be confused or you can have some shaking or feeling like your hearts racing, it can be a very uncomfortable feeling and since we know, especially in the intensive group you are more likely to experience this we just want you to be aware so you are not surprised. Most people who've had diabetes have experienced this in some degree but not everybody has. So if it is new to you I'd like you to know what that would feel like.

Serious hypoglycemia or low blood sugar may cause a loss of consciousness and if this occurs while you're driving or operating machinery it can really result in a terrible injury and could be life-threatening. But again, we ask that you test your blood sugars often so we can predict your patterns more and try to avoid this as much as possible. In very rare cases, hypoglycemia can be severe and require emergency treatment or hospitalization and severe low blood sugars can cause brain damage, coma and death and this can happen in any patient taking medication to lower blood sugar but it is more common in those taking insulin in the intensive treatment. So you usually juice or glucose tablets known as sugar pills can raise your blood sugar if you have those symptoms and if the low blood sugar is severe enough then sometimes it's going to require paramedics coming to the home and putting intravenous fluids or glucose into your vein (24:01) or giving you glucagon which is a medication that rapidly increases your blood sugar. But again, this risk is very small but it is a possibility. Regardless of which blood sugar treatment group you are assigned to, safety will always be a first importance when the changes in your management of your sugar are made. Based on data from previous studies it's estimated about 6 out of 100 participants will have a serious complication like a hospitalization, an emergency room visit for hypoglycemia and in the standard group about 2 participants may have that sort of a complication each year. In either group the ACCORD doctors and nurses will take to action to lessen the risk of hypoglycemia if it should occur too often or in a severe form. So that's again why frequent communication is really important. On the other hand participants in the standard group may have a somewhat higher risk of complications related to diabetes like eye, kidney disease, or abnormal nerve function (25:04) and its estimated that in the intensive group about 1 out of 100 participants will have a complication every year and the standard group about 1 ½

participants out of 100 may have such a complication every year. So again it is a small amount but it is a real risk of having these complications.

So if you are assigned to the intensive blood pressure group you may experience blood pressure that's too low and typically people can feel dizzy or light headed or feeling like they are about to faint so sitting down, moving slowly, that typically relieves these symptoms but if you experience any of these things I'd like you to let us know right away so we can adjust your treatment.

So now I'm going to talk about each of the medications that we could possibly be using in the study, the blood sugar treatments, the blood pressure treatments , and the cholesterol treatments. Now all the medication that I will be discussing here are standard medications that we use every day in our clinical practice. And we do know that any medication has a potential risk of having an allergic reaction and if we don't treat that right away it could become life threatening. So again if you experience any side effects it's really important that you let us know right away.

[here Elizabeth will tell the group that in a real conference the enroller would explain all the possible medication for all the arms of the study. It is a very long list and would take 20 – 25 minutes to explain. We can reference the pages in the consent form]

~~The blood sugar treatments, Sulfonylureas are the first class of medications. They've been around for a very long time. They work by causing your pancreas to make more insulin. Because we're causing your pancreas to make more insulin, the most common side effect in this family is low blood sugar. We can also see some weight gain because if you have too much insulin around it can cause you to be more hungry and you can also have allergies. There are also some very rare blood cell abnormalities that can occur but we always check your blood and make sure that that's not happening. Biguanids or metformin have also been around for a long time. Metformin mostly has side effects related to your digestive tract or your stomach. So commons side effects in this class can be nausea, vomiting, diarrhea, bloating, and loss of appetite or a metallic taste in your mouth. Usually we start at a very low dose and we increase this slowly so you don't have this side effect. If it continues then we would always reduce the dose or stop the medication. And very rarely people can have a severe reaction know as lactic acidosis which is when your body fluids have too much acid in them. And it almost always occurs in people who have advanced kidney disease, liver disease, or heart failure and in those who drink a lot of alcohol so we won't put you on this medication if you have any of those conditions. And again we're measuring blood tests to look at these risks.~~

Another group is an oral medication called a thizaolidinediones, which is a very large word, but it's a medication call rosiglitazone. Rosiglitazone is a tablet that you take. The most common side effects of this group include retaining fluids so you can have ankle swelling and that just causes you to hold too much water and it can cause weight gain. This is a very good medication at reducing your blood sugar but with the side effect that it can cause some swelling and some weight gain. This medication has been used in combination with insulin in research studies but then in this study we have the potential of using it with a higher dose and its possible that that could cause more fluid build-up and could worsen heart failure. Of course if you have heart failure we would not put you on this medication. Symptoms of heart failure, if you were to experience it, include feeling short of breath, having a cough, tiredness, ankle swelling or weight gain so please let us know if you do experience this. There was a report of an older medication in the same family that had caused liver problems so we do check liver function tests every once and a while just to be sure that that's not a problem, but nothing has been reported with this particular medication.

Then we talk about insulin and there's many different types of insulin. Insulin is an injection that you would take and sometimes it's a long acting insulin that lasts a whole day and sometimes it would be short acting insulins that you would take only with meals. (30:00) And the main side effect is having a low blood sugar if you take too much but we start at a very low dose and try to increase that slowly. Very rarely you can also have low potassium in the blood or an allergic reaction or a skin irritation from taking the insulin.

And the last medication family is one called Repaglinide or meglitinide. This is also a pill you would take before eating and the idea is to bring your blood sugars down after eating and common side effects include headache, upper respiratory infections, nausea, vomiting, constipation, and diarrhea. And the most serious side effect is low blood sugar. Testing your blood sugar frequently would help us figure out if you are having side effects from this.

Now there are many, many blood pressure treatments that are currently available and the one we chose for you to be on, if you are in the blood pressure arm of the study is dependent on many factors including your life style, taking it once a day versus twice a day and so we try to individualize the treatment so we get the best treatment for you. We know one medication is called an Ace Inhibitor or a Angiotensin converting Enzyme Inhibitor, common names are benazepril, Lisinopril, Ramipril, a lot of diabetic patients are on this. Potential side effects include dizziness, headache, fatigue, nausea, diarrhea, cough, rash, high potassium in the blood. Any of these blood pressure treatments can cause light headedness or dizziness if your blood pressure goes too low so again we

increase the dose slowly. Rarely you can have severe reactions, swelling of the face, lips, and tongue, called angioedema but again this is rare.

Diuretics are also known as water pills and most of the side effects include muscle cramps, nausea, vomiting, diarrhea, dizziness, rash, weakness, and low blood pressure. Low potassium can also happens so we're going to be monitoring your potassium levels, high blood sugars and then you can have some sexual function problems and gout, which is painful condition that occurs when too much acid and salt build up in the blood stream and joints.

Another class of medications are called Beta Blockers and the way they work is they slow down your heart rate. The most common side effects, because they are slowing down your heart rate, include dizziness, fatigue, stomach upset, depression, cold hands and feet, low blood pressure, changes in heart rhythm and heart rate, and a decrease in sexual function. And among people that have diabetes there are some reports that medications in this family they may hide some of these symptoms that you would get when your blood sugar goes low but not the hazards of low blood sugar so it's very important again that you test your blood sugar more often, particularly if you're on this medication.

Calcium Channel Blockers are another way of lowering blood pressure. Most frequent side effect of these are ankle or foot swelling, dizziness, flushing, palpitations, which is just sort of like a rapid heartbeat, you can also have headache, fatigue, nausea, and abdominal discomfort.

Alpha Blockers, they open up your blood vessels a little bit more and try to reduce blood pressure that way. Potential side effects in this category can be fainting, dizziness, fatigue, swelling, low blood pressure, and problems with your sexual function, heart rate changes and blood cell abnormalities.

Alpha II Receptor Blockers are another class of medication. Most of these medications have very similar side effects but the most common side effects are dizziness, headache, fatigue, diarrhea, muscular-skeletal pain. The more serious side effects are angioedema that we had mentioned, the swelling of lips, face, and tongue that can result in difficulty breathing and in rare cases, death, and severe low blood pressure. This family of drugs can also affect your kidney function so we will be doing blood tests to see if your kidneys are performing properly.

There is a medication called furosemide which is another water pill, it's called a loop diuretic, and these have side effects including low platelet counts, rash, pancreatitis which is an inflammation of the pancreas, jaundice, or yellowing of the skin or whites of the eyes indicating possible liver problems. (35:14) and serious side effects include abnormalities in the blood cells.

Reserpine is another medication in the family called Sympatholytics, and the most common side effects include dizziness, dry mouth, nausea, vomiting, nasal congestion, edema, which is a swelling in the body tissues, too much fluid in the body's tissues, stomach cramps, headache, impotence, which means difficulty with sexual function, depression, nervousness, shortness of breath, nightmares, difficulty in urinating, shaky hands and a poor appetite. These side effects have been seen in much higher doses than we would actually be using in our practice but they are listed regardless. More serious side effects include heart rhythm changes, black tarry stools, vomiting blood, slow heart rate, chest pain and low platelet counts.

The vasodilators – one medication in that family that we will be using is hydralazine and the side effects in this include headache, fast heart rate, chest pain, and palpitations or a feeling of rapid heart rate. Rare and more serious side effects include abnormalities in your blood cells and some symptoms associated with a condition called lupus, which can result in more fatigue and tiredness.

Potassium Sparing Diuretics, one is called triamterene the most common side effects include diarrhea, nausea, vomiting, gastrointestinal distress, or discomfort in your stomach, dizziness, dry mouth, itching, rash, sensitivity to light, weakness, low blood pressure, muscle cramps, blood chemical imbalances such as too much potassium, impaired kidney function, and then elevated uric acid, blood cell abnormalities and reduced folic acid stores. And there's always a risk of more serious side effects including acid in the blood and shock due to an allergic reaction to the medication. And in the beginning when we first put you on any of these medications we monitor you very closely for side effects and if there is any sense that you are experiencing any of these side effects then we will discontinue or reduce the dose.

The last medication in this blood pressure arm are called alpha blockers, carvedilol is one and the most common side effects are dizziness and fatigue. The more serious side effects include a heart rhythm disturbance, a slow heart rate, a low platelet count, and bronchospasm or tightening of the breathing airways. Alpha-beta-blockers may also hide some of the symptoms but not the hazards of low blood sugar. So those are the many

medication that we could use in the blood pressure arm of the study if you were enrolled in that portion.

Now the cholesterol part of the study. Everyone that would be in the cholesterol part of the study would be on a medication called simvastatin. The common side effects in this medication include headache, dizziness, upset stomach. Rare, but more serious side-effects are muscle aches, rash and elevated liver enzymes so in the beginning of the study when we first put you on it we will be asking you questions about any experiences with muscle aches and we'll be measuring some blood tests at the beginning and then also shortly after you start taking the medication to be sure that that's not happening.

Now if you are in the cholesterol part of the study and you are assigned to the fenofibrate group; fenofibrate is a medication that has been associated with abdominal pain, gall bladder stones, and jaundice which is yellowing of the skin or eyes indicating liver problems, It can also be associated with headache, change in taste, elevated kidney and liver tests and certain abnormalities in the blood cells. So if you are on finofibrate or the placebo we'll be measuring your liver and kidney tests.

So all of these medications, as I said, are available and are used in clinical practice (40:00) most have been used for many, many years. But we know much about how each of the individual drugs work and how they interact with other drugs, especially other treatments that will be used in the study. One medication called sulfonylurea which is a diabetes pill is not to be used with other certain drugs and so your doctor in the study will make sure that we don't have any interactions that could cause problems.

And we also know that using the cholesterol medication called statins or simvastatin and fibrates together could possibly increase your chances with problems with the liver and muscle pain and inflammation and these are very rare, but at higher doses they're more likely and so if we have to increase your cholesterol medication simvastatin to 40 mg a day your chance of side effects may be increased and so we will use caution whenever you are given a combination of simvastatin and fenofibrate. Many doctors do use this combination and we have received permission from the FDA to test this combination. Also, the accord clinic will be checking your blood to make sure the study medications are not harming your liver or your muscles and that will be done at the beginning and then at 4, 8, and 12 months and then every year after that. And if at any point you feel that you are having muscle pain or any side effects then we can always test this more frequently or on a as needed basis. And if looks like the combination of these medications is causing a problem then we may take you off of one or both of these medications.

~~And if you are on the lipid portion of the study and you're on Coumadin which is a blood thinner also known as warfarin your own doctor will be informed by phone and in writing that you may be on the fenofibrate because the use of fenofibrate generally means that your dose of Coumadin should be reduced so that you aren't at lower risk of having bleeds, we'll just make sure your doctor knows about that.~~

So what are the benefits? So we don't know if the ACCORD treatment either the standard or the intensive group or the blood pressure or the cholesterol arms of the study will actually benefit you personally, but we do know that gathering this information will help future generations and possibly your own generation just to know what's the best way to treat Type 2 diabetes and there is going to be no charge to you for any of the treatments that we use in the study or any of the testing supplies, visits or laboratory exams and your doctor will be notified of all of these results. But you will not be paid for your participation in the study but all the testing supplies and everything will be free of charge.

And what are the alternatives? Well as we're actually using medications that are used in clinic, you can have the same sort of treatment with your own primary care doctor and that's your alternative is that you would just have your diabetes and blood pressure and cholesterol managed by your own doctor including diet, exercise, weight loss all as treatments for your diabetes.

And as part of our study you would also be given an opportunity to work with our dietician and diabetes educators to do very similar things.

If you have any sort of research related injury throughout the study, it's not likely that you would suffer any major health problems by participating in the study but there's always a small risk of having serious health complications and if that should occur, treatment would be available including first aid, emergency treatment and follow-up care and they'll just be billed in the ordinary manner to your insurance company, it's not paid for by the study.

As far as confidentiality we want to protect your privacy so any information that we gather about you during the study will be treated as strictly confidential and we will be assigning you a code number if you participate in this study so there will be no name or information about you associated with your name. However, your name and Social Security and Medicare numbers will be recorded and stored centrally to help the study keep track of any illnesses you may experience and if you order free testing supplies to measure your own blood glucose you need to provide the information so that we can bill

it to Medicare or any insurance you may have. (45:02) And if you don't have Medicare or other insurance then the study will cover the cost of that. And when we publish the data there will be no identifying features about you in the publication. At the end of the study, then all the forms with your name and other identifying information will be kept in a locked room for up to five years and only your study doctor or co-workers assisting the doctor will have any access to these forms. After five years, the forms will be destroyed.

Any blood, urine and tissue samples that we have taken from you during the study will be considered donated by you to medical research. And these materials may also be provided to the National Heart Lung and Blood institute at the end of the study, again, with no personal identifying information but it may be shared with other scientists who meet the requirements so that we can learn more about diabetes and related problems. Drug companies that have contributed drugs, and in some cases money, to the ACCORD study will also be provided study data but again with no personal identifying information.

It's important for you to know that ACCORD has been granted a Certificate of Confidentiality form the US Government to make sure that we protect your privacy. This means that the ACCORD researchers cannot be forced to tell anyone that's not connected with the study about your participation. And this includes courts and police. The researchers will only release information if you request it yourself.

There are some limits to the researcher's ability to maintain your confidentiality. If we learn that keeping information private would immediately put you in danger, or put someone else we know in danger, then we will have to tell the appropriate agencies to protect you or the other person.

So your participation I this study is completely voluntary. You may choose at any time in the study to withdraw or end your participation with us and there will be no penalty or loss of any benefits to you if you decide you don't want to participate in this study anymore and your study doctor also has the right to stop your participation in the study at any time if they feel necessary. This could be because you had an unexpected reaction, or if you have failed to follow instructions, or because the whole study had been stopped early.

So any new information that we gather about the study or anything that may affect your health, welfare, or willingness to stay in the ACCORD study will be shared with you and results of your lab tests and clinical measurements will be provided to you to share with your own physician.

Now I'd like to ask you what question you have for me, I'd be happy to go through any areas that are not clear to you, just so that we're sure that you understand what is expected of you. I'd like to you to explain in your own words what we're asking you to do.

I do want to go through some contact phone numbers that if you have at any point a question that you would feel more comfortable with talking with somebody that's not involved in the study we have a Fairview Research helpline with the contact information below and if you'd like to talk to our main study investigator, Dr. Seaquist, her contact information is here as well.

Now I'll just briefly talk about the genetic studies. Again, genetic studies are an extra part of the study. You don't have to participate in the genetic study to be part of the main ACCORD trial. One of the goals in ACCORD is to examine your genetic material and its relationship to the effects of the treatments. If you volunteer to participate in the genetic studies you'll be asked for a sample of blood, about 1 teaspoon to obtain DNA from your blood cells, DNA is just the genetic material in your blood cells. What will happen to the DNA samples? Well, we'll examine directly your DNA or create a living tissue sample or a cell line and this gives researchers an unlimited supply of DNA that they can use in the future without having to draw more blood from you. And it's not a human clone of you but it's just more cells from that small sample you give us (50:03) to begin with.

Will we share the DNA with any other institutions? With your permission, the ACCORD Central Laboratory may share DAN samples with researchers participating in the ACCORD study. If you give permission, samples may also be shared with other research laboratories studying the genetics of type 2 diabetes and the development of heart and blood vessel diseases, other major diseases, health conditions, or risk factors. The scientists from these laboratories would be given the DAN and there is no information about you in there.

And how will they be used in the future, these samples? Information gained from research on your cell line may be used to develop new ways to detect or treat major diseases.

And how will we keep this genetic information private? Only the ACCORD study data manager will have access. No other individual, including your spouse, parents, children, physician or employer will have access to the stored sample or information gained from your stored sample. At the end of the study, your samples may be provided to other investigators under certain conditions, without any personal identifying information.

How long will the DNA samples be kept? Your sample may be kept until it is no longer of scientific value. If, at any time during the study, you decide that you do not wish to have your DNA sample stored any longer, the sample will be destroyed.

Who owns the sample? By checking "yes at the end of this document, you volunteer to provide genetic samples for medical research purposes. Your cell line or DNA will not be sold to anyone or to institutions or companies for financial gain or commercial profit without your consent. However, neither you nor your heirs, meaning possibly your children or spouse will receive any money from any discoveries or inventions made using the information and/or specimens you provide.

Will you receive study results of research involving your samples? This is not a clinical test so it's not used to give you an specific information about your own health or genes so you will not be informed of any of the results of the research performed on your genetic blood sample. Although a genetic test may be developed after a study of samples in the ACCORD study. If there is any new information about genetic testing for type 2 diabetes and its relationship to heart and blood vessel diseases or other health conditions, you will be informed by your study doctor if this information may be important to you or your family. And there is no cost to you for any of this. So if you decide you would like to participate in the genetic portion you have three options.

One is to check 'Yes, I agree to participate in the genetic portion of ACCORD and to allow a living tissue sample to be developed for future genetic studies" or you have the option of just agreeing to participate in the genetic portion but not having a cell line developed or you can decide you do not want to participate in the genetic portion.

And then you can also choose which conditions you would like your genetic sample to be studied if you decide you want to participate so you can chose any major disease or health condition or risk factors or you can choose only for genes related to diabetes, blood pressure, blood cholesterol abnormalities, heart disease, other cardiovascular diseases, kidney disease or other risk factors for heart disease and then if you agree to participate in the genetic portion then we want you to check one of the following involving the investigators who will have access to it. So you can choose to allow the genetic samples to be used for research by the ACCORD investigators as well as by other researchers who meet the standards and procedures for the National Heart Lung and Blood Institute or you can decide you would only like your genetic samples to be used only for research by ACCORD investigators.

So that was a lot of information and I know you probably have more questions regarding this. I would be happy to answer any of them. Now that we've reviewed the consent form together I'd like you to take some time to actually think about it before signing. This is a big commitment on your part and on our part as well and I want to be sure you feel comfortable with the study before you actually enroll in it so I'd be happy to take any questions that you have and if you could explain to me what you think we are asking you to do then we can be sure you understand the study completely.

Appendix X

Demographic Data Study 3

Age Range	Years in the U.S.	Country of Origin	Level of English	Years of Education
	30	Mexico	1	0
26–35	15	Mexico	1	> 12
36–45	15	Mexico	1	1–6
46–55	17	Mexico	5	7–9
46–55	22	El Salvador	1	7–9
36–45	12	Mexico	1	>12
56–65	12	Mexico		1–6
46–55	5–10	El Salvador	1	0
56–65	14	Ecuador	1	0
56–65	11	Mexico	1	1–6
56–65	15	Mexico	1	7–9
46–55	15	Mexico		1–6
36–45	19	Mexico	1	0
46–55	11	Mexico	1	0
36–45	15	Mexico	5	>12
	6	Ecuador		
46–55	16	Ecuador	4	0
36–45	22	Mexico	1	1–6
36–45	12	Mexico	4	>12
36–45	12	Mexico	2	4–9
26–35	12	Mexico	2	7–9
26–35	19	Mexico	2	7–9
46–55	6	Ecuador		1–6
36–45	5–10	Mexico	1	1–6
56–65	24	El Salvador	4	7–9

Appendix Y

Process for Translation

Figure 2
Study Flowchart of Translation Process